Critical Access Hospital CoP Part 3 of 5

Physical Plant & Environment, Emergency Preparedness, Staffing Provision of Services: Pharmacy, Dietary & Nutrition

Speaker



- Laura A. Dixon, Esq.
- BS, JD, RN, CPHRM
- President, Healthcare Risk Education and Consulting, LLC
- ldesq@comcast.net
- Email questions to CMS: QSOG_CAH@CMS.HHS.GOV

2

DISCLAIMER

The information provided during this program/webinar is informational only. It is not intended to be legal advice or to establish an attorney-client relationship. Please consult with your in-house counsel or professional legal representative for advice.

Objectives

- Describe: Emergency Preparedness training and testing requirements for a Critical Access Hospital
- Explain: responsibilities of pharmacist that include developing, supervising and coordinating activities of the pharmacy
- Recall: requirements for security and storage of medications, medication and anesthesia carts
- Discuss: requirements for dietary to meet nutritional needs of patients and requirements of a dietitian



Physical Plant & Environment

Tag Nos. C0910 - 0944

Condition: Physical Plant & Environment C0910

- Applies to
  - All locations
  - All campuses
  - All satellites
  - All in-and out-patients
- Departments/services responsible for building and equipment/maintenance must be incorporated into QAPI

Construction C0912

- Standard: Hospital constructed, arranged, and maintained
  - Ensure access
  - Safety of patients
  - Provide adequate space to provide care to patients
- Constructed per state and federal law
  - Will look to see if maintained to ensure safety of patients
    - Conditions of ceilings, walls, and floors
    - See Facility Guideline Institute (FGI)*

*See Appendix

Maintenance C0914

- Standard: CAH has housekeeping and preventive maintenance programs
- All essential mechanical, electrical, and patient-care equipment maintained in safe operating condition
  - Facilities, supplies and **equipment** must be maintained



Equipment

- "Equipment" includes:
  - Boilers – elevators – air compressors – ventilators – x-ray equipment – IV pumps & equipment – stretchers – maintenance log, etc..
- Identify equipment to meet patient needs in case of an emergency/disaster situation
  - Mass trauma – disease outbreak – internal disasters, etc..
- All equipment must be tested and inspected before initial use and after major repairs/upgrades*

* See Appendix

Interpretive Guidelines

- All equipment must be
  - Inspected, testing and maintained
  - Ensure safety, availability and reliability
- Activities may be done by
  - Employees
  - Contractors
  - Combination

Individual Over the Program

- Individuals overseeing program must be qualified
  - Must maintain records to show individuals qualified
- Overall - must demonstrate
  - Qualified personnel
  - Performing risk-based assessments, PM
  - OR – establishing the AEM program

Policies and Activities

- Must have policies, procedures and programs re:
  - Inventories
  - Activities
  - Schedules
- Follow manufacturer-recommended activities and schedules
  - Can do more frequently
  - But must use recommended activities
  - Maintain documentation

Question

Beecher Critical Access hospital's plant manager retired after 40 years at the site. During that time, he was responsible for ensuring all equipment, including any newly acquired equipment, was inspected and routinely maintained. Beecher was without a replacement for 6 months during which time 2 used generators from a closed facility were installed but not inspected nor added to the master equipment list. During a major storm, both generators failed leaving critical care areas without power.

- Will Beecher be cited?
  - Yes
  - No
  - Not sure

Alternate Equipment Management

- Can use maintenance program different from manufacturer recommendations
  - "Alternate equipment management" - AEM
- Must develop, implement and maintain documentation
  - Minimize risk to patient and others with equipment use
  - Be based on generally accepted SOP
  - Example: American National Standards Institute for the Advancement of Medical Equipment Handbook

Equipment Placed in AEM

- Must verify qualified employees/contractors
  - Making the decision on placement
  - Performing risk-based assessments
  - Establishing AEM requirements
  - Managing the program
  - Performing maintenance per the AEM policies and procedures

Who Qualified for AEM Decision

- Medical equipment
  - Clinical or biomedical technician or engineer
  - Specialized/complex equipment – may need specially trained person
- Facility equipment
  - Healthcare Facility Management professional
  - Facility manager/director/VP facilities
- Must maintain records of qualifications
  - Demonstrated how assure contractors qualified

Equipment in the AEM Program

- Expected to identify critical equipment
  - Either biomedical or physical plant equipment
  - Where risk of serious injury or death if fails



Factors to Consider

- How equipment used and consequences of failure
  - Seriousness of harm if fails
  - How widespread the harm – one or many
  - Information on equipment maintenance recommendations
  - Maintenance requirements – simple to complex
- Timely availability of backup systems
- Incident history of same/similar equipment

Equipment NOT Eligible for AEM

- Federal or State law requiring maintenance, inspection and testing done per manufacturer's recommendations
- Other CoPs requirements – National Fire Protection Association Life Safety Code
- Radiology/imaging equipment
- Medical laser
- New equipment with insufficient maintenance history

Frequency of PM

- Based on nature of equipment and risk to patients/staff health and safety
- Must follow manufacturer's recommendations
- Nationally recognized expert associations
- CAH's experience
- Must adhere strictly to activities or developed



Inventory

- Expected to have list of facility and medical equipment essential to operation of the CAH
- For low cost/risk essential equipment – housekeeping – can list the number under an item
  - Vacuum cleaners
- Other:
  - AEM equipment must be readily separately identified as such
  - Critical equipment must be readily identified as such

Survey Procedure

- Will interview personnel in charge of maintenance
  - Adequate provisions for availability
  - Equipment identified as essential
    - Regular
    - Emergency situation
- Determine if complete inventory of equipment to meet patient needs

Survey Procedure – continued

- Review documentation of responsible personnel qualifications
- How assures contractors use qualified personnel
- If following manufacturer-recommended maintenance activities and frequency
- If using an AEM
  - Will look at a sample of equipment in AEM program
  - Maintenance strategies and how performed
    - Including critical equipment - ventilators

Disposal of Trash C0920

- Proper routine storage and prompt disposal of trash
  - Interpretive guidelines are pending
  - Reference only - previous interpretive guidelines
    - Includes biohazardous waste
    - Must be disposed of in accordance with standards (EPA, OSHA, CDC, environmental and safety)
    - Includes radioactive materials
  - Survey procedures pending



Storage of Drugs C0922

- Drugs and biologicals must be appropriately stored
  - Properly locked in the storage area
  - Medication carts in C-section rooms locked
  - Drugs not left out in tube system/dumbwaiter ledge
- Surveyor will ask what
  - Standards
  - Guidelines
  - Law using

Physical Environment C0924

- Premises clean and orderly
  - Uncluttered physical environment
  - Where patient/staff can function safety
  - Equipment/supplies properly stored
    - Not in corridors
  - Spill not left unattended
  - No floor obstructions
  - No evidence peeling paint, visible water leaks or plumbing problems



Ventilation, Lighting & Temperature C0926

- There is proper ventilation, lighting and temperature control:
  - Pharmaceutical
  - Patient care
  - Food preparation
- Interpretive guidelines and Survey procedures pending

CMS Memo April 19, 2013

- CMS: if no state law, hospital can write policy or procedure or process to implement the waiver
- Waiver allows RH between 20-60%
- In anesthetizing locations – see definition in memo*

- * See Slide 145

Impact of Lowering the Humidity

- Equipment and supplies
  - Shelf life and product integrity of some sterile supplies
    - EKG electrodes
  - Electro-medical equipment may be affected by electrostatic discharge
    - Especially older equipment
  - Erratic behavior of software and premature failure of the equipment
  - Calibration of the equipment
- Follow the manufacturers instructions for use that explains any RH requirements

Life Safety From Fire C0930



- Standard: Except as otherwise provided
- Follow LSC provisions
- Includes NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4
- Have positive latching hardware and no roller latches on doors where flammables/combustibles stored
- Interpretive guidelines are pending

LSC Provisions Waiver C0932 - 0936

- LSC waiver – would cause unreasonable hardship (C0932)
  - Cannot affect the health or safety of patients
- Must maintain written evidence of regular inspections by the state fire control agencies (C0934)
- Can install alcohol-based hand rub dispensers if done in manner to protect against inappropriate access (C0936)
- Interpretive guidelines and Survey procedures pending for all three

Sprinkler System C0938

- If the system is shut down for more than 10 hours must:
  - Evacuate the building or portion of the building affected
    - Until the system is back up, or
  - Establish a fire watch until the system is back up
- Interpretive guidelines and Survey procedures pending

Sleeping Rooms - Windows C0940

- Every sleeping room must have an outside window or door
  - Constructed after 7-5-16:
    - Sill height can be higher than 36 inches about the floor
    - Does not apply to newborn nurseries for intended occupancy of less than 24 hours
    - Special nursing care area of new occupancies shall not exceed 60 inches
- Interpretive guidelines and Survey procedures pending

LSC Provisions C0942 & 0944

- CMS can consider recommendation of state survey agency or accreditation organization for LSC waiver if would pose undue hardship (C0942)
- Must meet the Health Care Facility Code (0944)
  - NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6
  - May grant waiver if unreasonable hardship and does not affect health or safety of patients
- Interpretive guidelines and Survey procedures pending

Physical Plant –Life Safety

- Added that in consideration of recommendation from State survey agency or AO – will waive for appropriate period of time some provisions of Life Safety Code
  - Cannot adversely affect health and safety of patients
- Added in references of National Fire Protection Association TIA code sections
  - See page 11 of the August 2025 notice



(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, *www.nfpa.org*, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]



Emergency Preparedness

Appendix W and Z

Question

Prairie hospital experienced a storm with hurricane-force winds resulting in partial loss of its roof. Patients were moved from the involved area and Prairie activated its Emergency Preparedness plan. After 6 months, Prairie reopened and evaluated its response to the event, identifying 2 areas for improvement. Prairie was due for its annual full testing exercise.

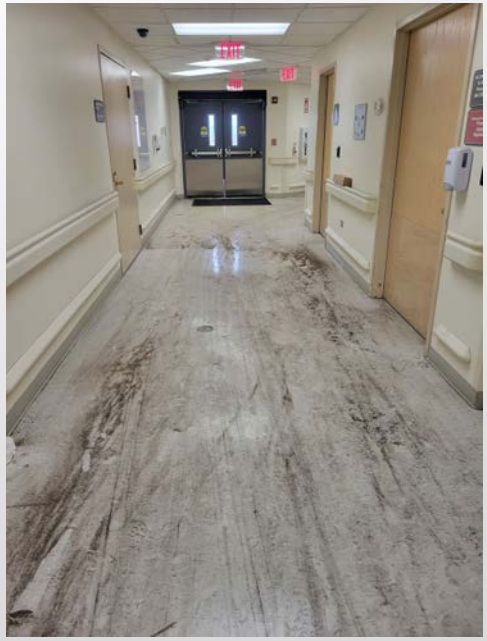
Can Prairie use the event as part of its testing requirement?

- Yes
- No









Small Hospitals Impacted



(Image from Mercy)

MARIETTA, Okla. — Mercy Health Love County hospital is closed after being struck by a tornado.

Any Disaster



Emergency Preparedness

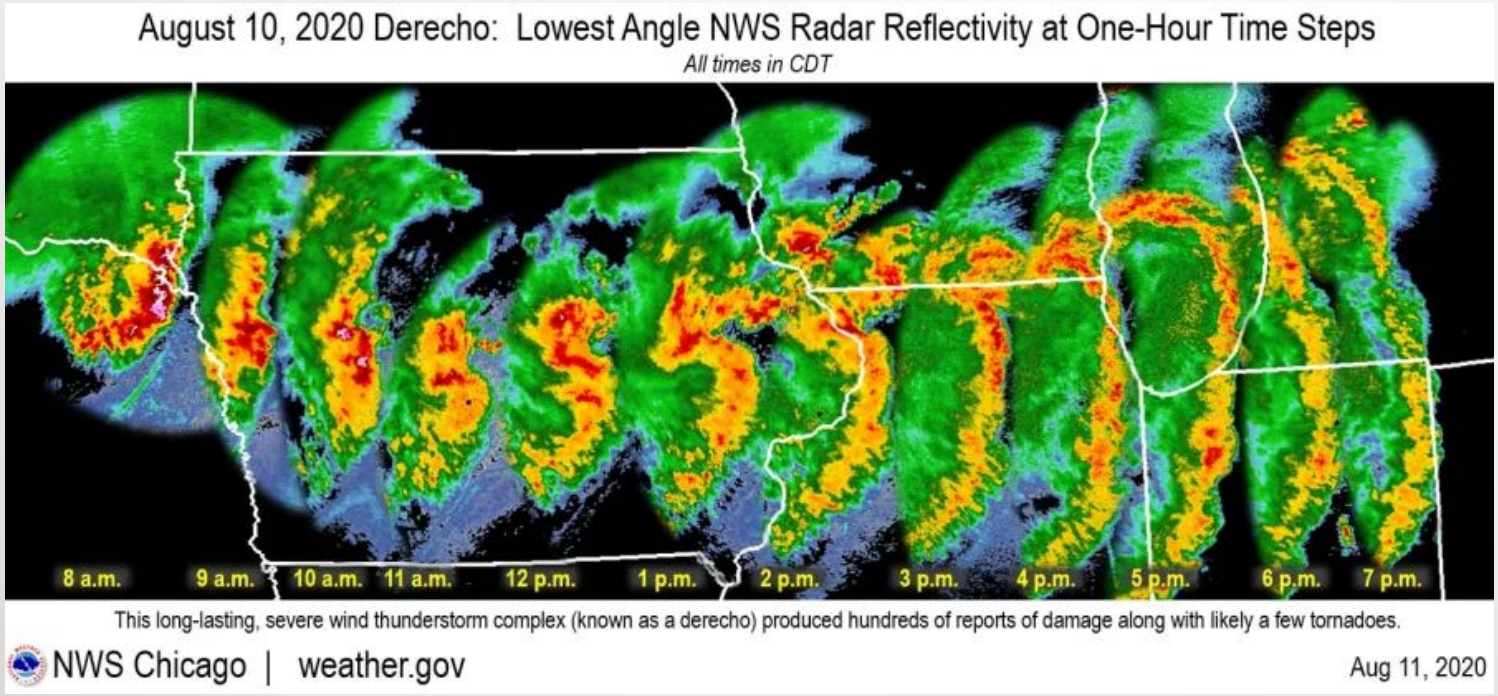
- Regulation only still in Appendix W
  - Starts at tag C0950
- Requirements, interpretive guidelines and survey procedures in Appendix Z
- Will be surveyed during certification and validation surveys



Emergency Preparedness C0950

- **Condition:** Must comply with all federal, state, and local emergency preparedness (EP) requirements
  - Have and maintain a comprehensive EP program
  - Utilize all-hazards approach – including emerging infections
- Program must include:
  - Plan >Policies & procedures
  - Communication plan >Training & testing
  - Emergency & standby power

All Hazards – "Possible" To Occur





Man-Made Emergencies



Emergency Plan

- Reviewed and updated every 2 years
  - Based on and include documented facility & community-based risk assessment
    - Using all-hazard approach
  - Include strategies for addressing emergency events identified by the risk assessment
  - Address patient populations, persons at-risk, types of services that can be provided and succession plans
  - Include process for cooperation and collaboration with EP officials

Policies & Procedures

- Based on the plan, risk assessment and communication plan
  - Reviewed and updated every 2 years
- Address:
  - Provision of subsistence needs
    - Food-water-medical-pharmaceutical supplies
    - Alternate sources of energy – for services
  - System to track off-duty staff/sheltered patients in the hospital

Policies & Procedures (cont'd)

- Address – cont'd
  - Safe evacuation
  - Means to shelter in place
  - System of documentation – preserves confidentiality
  - Use of volunteers/other staffing strategies
  - Arrangement with other CAH/providers

Communication Plan

- Plan that complies with all laws
  - Reviewed and updated every 2 years
- Must include
  - Names/contact information – patients/staff/physicians
  - Contact information – emergency preparedness staff
  - Primary and alternate means communication
    - Staff
    - Emergency management agencies

Communication Plan – cont'd

- Must include (cont'd)
  - Method for sharing information/documentation of patients
  - If evacuate – means to release patient information as permitted
  - Method to provide information about condition/location of patients
  - Means to provide information about occupancy/needs/ability to provide assistance

Training and Testing

- Must develop and maintain training and testing program
  - Based on emergency plan
  - Risk Assessment
  - P&P
  - Communication plan
  - Reviewed and updated every 2 years

Testing

- Conduct exercises twice a year
  - One – must participate in full-scale exercise community or facility based
  - If actual disaster – exempt from next full-scale exercise
  - Two – conduct annual additional exercise of choice – full-scale, mock or table-top
  - Analyze and document all drills – revise as necessary

Exemption for Testing

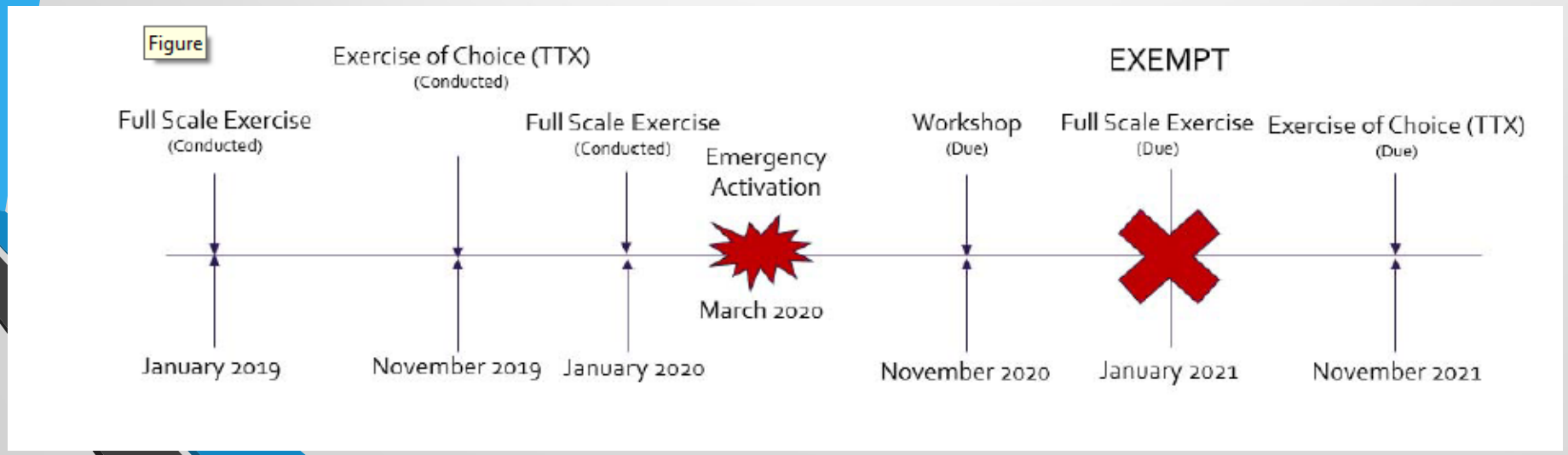
- If still operating under currently activated emergency plan during specified 12-month cycle of testing
  - Any currently-activated plan will be recognized as meeting the full-scale exercise requirement for that 12-month cycle
- If claimed exemption and have since resumed normal status – must complete required full-scale exercise
  - UNLESS – reactivated for an actual emergency during the 12-month cycle for that year

Exemption Example #1

- Facility conducted full-scale exercise January 2019
- Tabletop November 2019
- Another full-scale January 2020
  - Workshop was scheduled for November 2020
- March 2020 activated emergency preparedness
- Resumed normal operating status December 2020

Example #1 – What Next

- Must conduct workshop November 2026
  - Exempt from next required full-scale January 2027
- Expected to complete exercise of choice November 2027 and resume normal cycle
  - Next full exercise January 2028 and exercise of choice November 2028

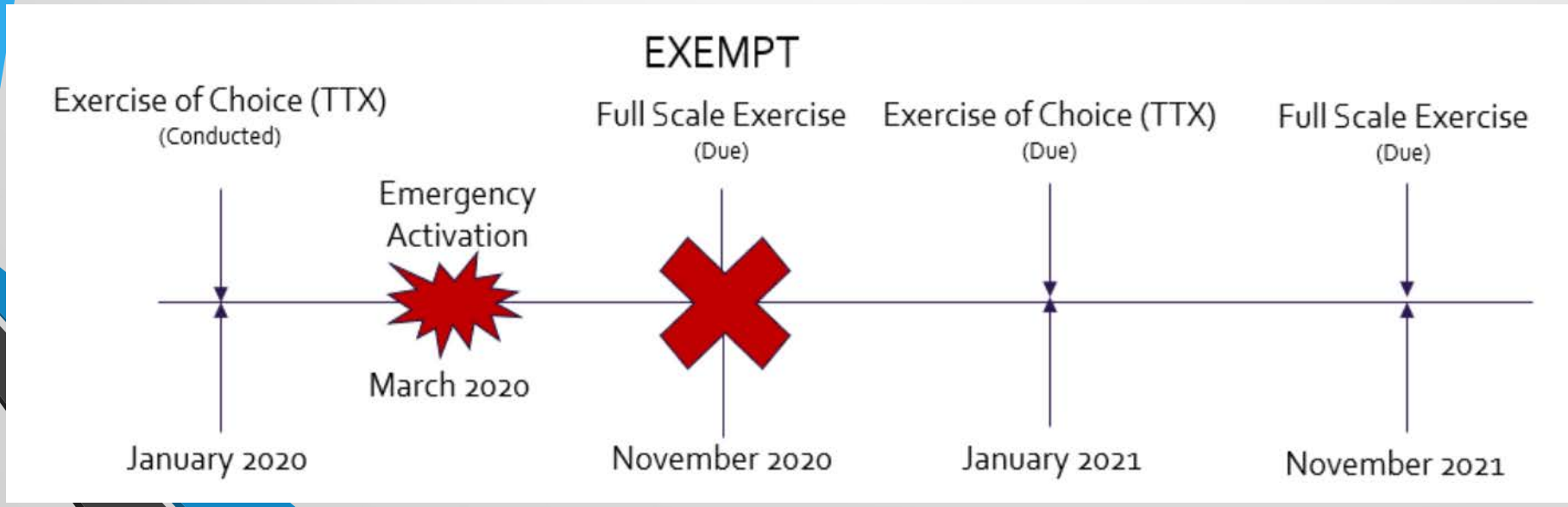


Exemption Example #2

- Facility conducted table-top January 2020 – exercise of choice
  - Scheduled full-scale November 2020
- March 2020 activated emergency preparedness program
- In 2021 – returned to normal operating status

Example #2 – What Next

- Facility exempt from November 2020 scheduled full-scale exercise for "annual year"
- Must conduct **both** full-scale and exercise of choice 2021 based on its defined cycle (Jan. and Nov.)
  - Returned to normal operations and required to conduct full-scale in Nov 2021 and exercise of choice Jan 22

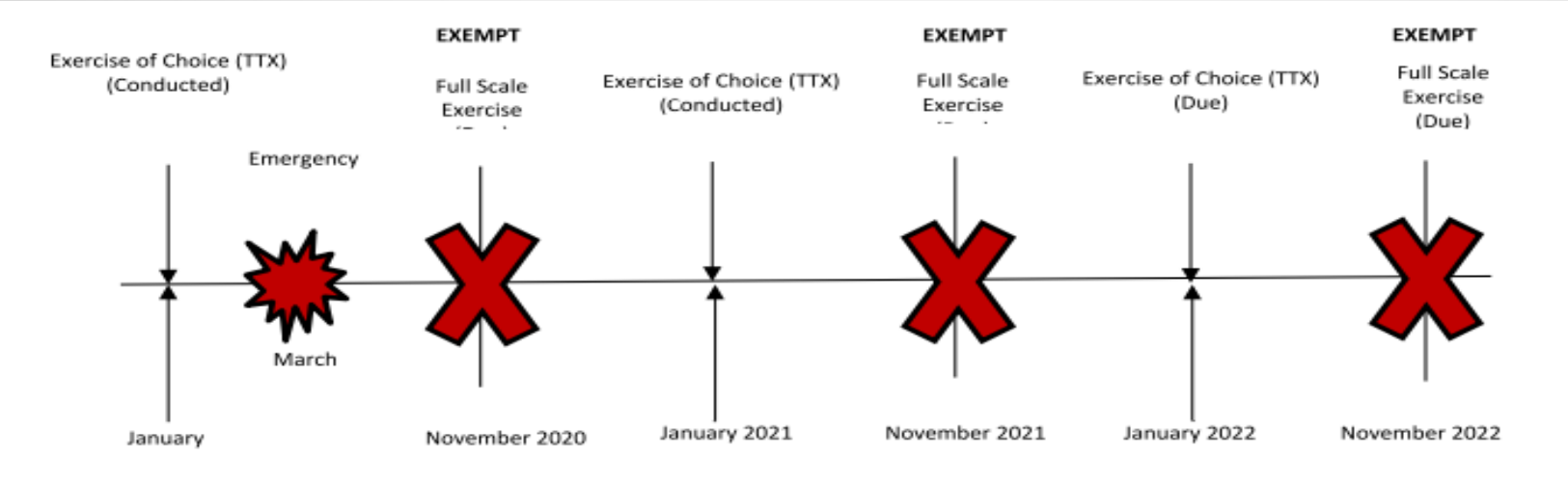


Exemption Example #3

- Facility conducted table-top Jan. 2020 and was exempt from scheduled full-scale in Nov – activated emergency plan
- Continues to operate under activated emergency plan during 2021 cycle

Example #3 – What's Next

- If still operating under active emergency plan any currently-active emergency plan will be recognized as having met full-scale exercise requirement for 2021 and 2022.
- Would continue to conduct exercise of choice in January 2021 and 2022

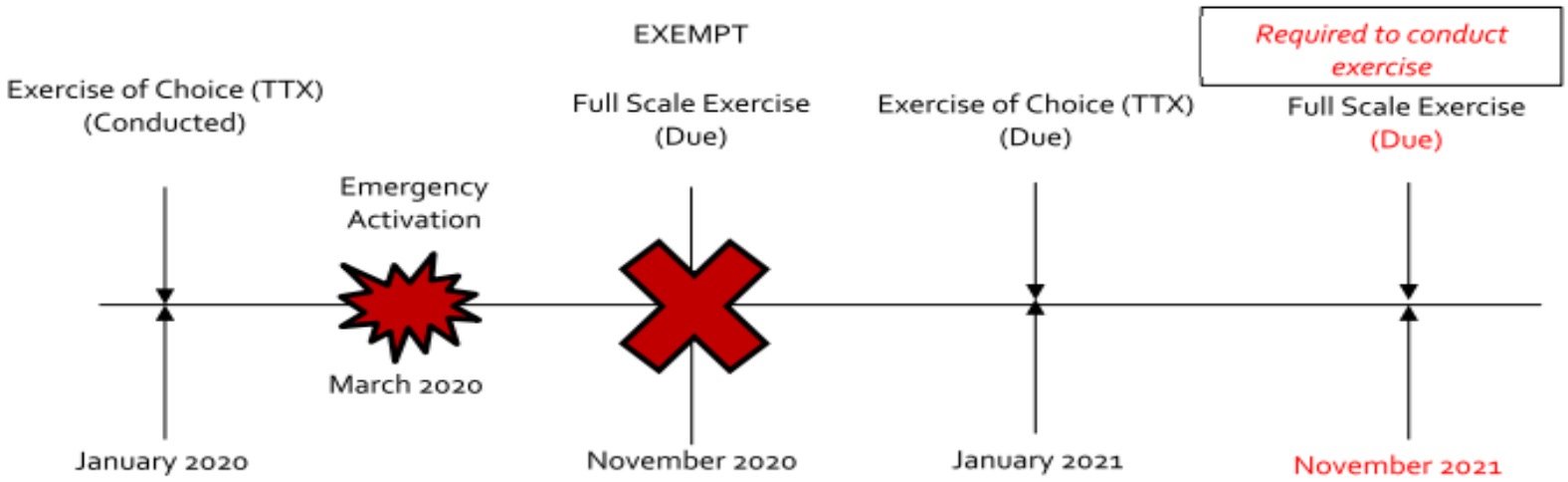


Exemption Example #4

- Facility conducted table-top in Jan. 2020 as exercise of choice
- Was exempt from scheduled full-scale exercise in Nov. 2020 – activated emergency plan in March
- Facility resumed normal operations in March 2021

Example #4 – What Next

- As the facility no longer under the activated plan
  - Did not reactivate during same 12-month cycle
  - Required to conduct next full-scale or individual facility-based exercise when due
  - Is required to resume 12-month exercise cycle
- Next required full-scale due in Nov. 2021



Survey Steps: Determine Exemption

- Will determine annual cycle
- Verify has conducted 2 required exercises within 12-month period
  - Will be exempt from 2021 and 2022 full-scale if still currently operating under activated emergency plan or reactivated plan
- Asked to describe exemption
  - To ensure facility understands exemption based on scheduled next-required full-scale exercise
    - Not exercise of choice

Survey Steps & Documentation

- Will verify documentation evidence that facility activated emergency plan
  - To determine if testing exemption acceptable for use
- Documentation may include:
  - Notice of activation to staff – alerts
  - Proof of patient transfers/changes in daily operations
  - Initiation of additional safety protocols – mandate PPE
  - Coordination with state/local emergency officials

Survey & Documentation – cont'd

- Documentation – cont'd:
  - Minutes of board/facility meetings
  - 1135 Waiver – individual or blanket
  - Incident command system related reports
- Determine if facility compliant with clause and conducted appropriate required exercises

Power Systems

- Implement emergency & standby power systems
  - Emergency generator location – per Health Care Facilities code and Tentative Interim Amendments
  - Generator inspection and testing
  - Generator fuel



Other Items to Consider

- If do not own the structure – must discuss emergency preparedness concerns with landlord
  - Ensure continuity of care if structure/utilities impacted
- Other considerations
  - Staffing – possible shortages
  - Surge capacity – taking in additional patients
  - Evacuation plans
  - Back-up evaluation plan – should nearby facilities also be affected and unable to receive patients

Delegation and Succession Plan

- Must address how patients receive care – in house or transferred
  - Circumstances transfer occurs
- Intent – ensure continuity of operations
  - Are different from "continuity plans"
- Documented plans to outline specific individual and alternate/successors
  - Who can activate emergency plans to ensure patient safety protected to ensure patient safety

Integrated Healthcare Systems NEW

- If part of multiple separately certified-healthcare facilities that elects to have unified and integrated emergency preparedness program
- Can choose to participate and if so, must do all:
  - Demonstrate actively participated in development of program
  - Developed and maintained in way to consider each facility's unique circumstances, population, services
  - Capable of actively used the program and is in compliance

Integrated Systems – cont'd

- Plan includes community-based risk assess using all-hazards approach
- Individual facility-based assessment using all-hazard approach
- Include integrated
  - Policies and procedures
  - Coordinated communication plan
  - Training and testing programs that meet requirements



Staffing and Responsibilities

Tag Nos. C0970 – 0999

Staffing C0970 & 0971

- **Condition:** Staffing and staff responsibilities
- Standard: CAH has professional staff that includes
  - One or more physicians
  - May include PAs, NPs, or CNS
- Need an organizational chart – shows names of all providers
- Surveyor will review work schedules

Staffing and Supervision

- All ancillary staff are supervised by professional staff (C0972)
  - Will look at organizational chart
- Sufficient staff to provide services essential to operation of the hospital (C0974)
  - Emergency services, nursing services, etc..
- Surveyor review schedules and daily census records
  - Adequate staff and supervision

Provider Available C0976

- MD, DO, NP, PA, or CNS must always be available to provide services
  - Practitioner available and shows up when patient presents to the hospital
  - Does not mean they have to be there 24 hours a day
- Must provide diagnostic/therapeutic services/ supplies commonly furnished in a physician's office

Nurse on Duty C0978

- Must have a RN, CNS, or LPN on duty whenever there is one or more inpatients
- Surveyor will review staff schedules



Provider Responsibilities C0980 – 0982

- Standard: Responsibilities of MD/DO
- MD/DO must provide medical directions and supervision of staff
  - Surveyor will verify physician available for consultation and supervision of staff (C0981)
- PA/NP must participate in developing/reviewing written P&P (C0982)
  - Want evidence physician participated
  - Ensure physicians review the policies periodically

Supervision C0984 & 0986

- Periodically review/ sign off all charts/orders of PA and NP
  - And as per state law
  - Surveyor will look for documentation of supervision (C0984)
- Plus – periodic review and sign off sample outpatient records
  - CMS recommends sample size of 25% all outpatient encounters managed by non-physician practitioners

Supervision – cont'd

- No specified time frame for periodic review
  - Time frame in the P&P
  - Maximum interval between inpatient reviews
- Consider volume and types of services provided in developing the P&P
  - 4 bed CAH would have different time frame than a 25 bed CAH
  - Does the CAH have EHRs that can be reviewed and signed off remotely?

Medical Direction Co988

- MD/DO must
  - Be present sufficient period of time
  - To provide medical direction, supervision and consultation
  - Available via direct radio/telephone communication
  - Amount of time "present" – on-site – not specified

Other Requirements

- Biweekly visit might be burdensome – especially for a small CAH in a remote area with low patient volume
  - Author's note: keep EMTALA law in mind
- MD, DO, PA, CNS, or NP must be on call and available to provide emergency care
  - Must have list of on-call physicians

PA, NP, CNS Responsibilities

- Standard: PA, NP, CNS responsibilities (C0990)
- Participate in development, execution and review of policies (C0991)
  - Be a member of the CAH staff
  - Surveyor: will interview mid level providers to determine participation and knowledge of policies
- Need to participate with MD/DO in review of the patient's medical records (C0993)

PA, NP, CNS – Duties

- Perform functions not being performed by the physicians (C0995)
- Refer patients if needed services cannot be provided at the CAH (C0997)
  - Make sure medical records are maintained
- Notify physician when patient is admitted by midlevel (C0998)
  - Document patient is under the care of the MD/DO

Patient Transfer – Author's Notes



- Send a copy of the patient's medical records
  - Unless can access electronically
- Have a transfer policy – consistent with EMTALA
- Provide EMTALA training to staff, providers and on-call physicians

Question

Moser CAH employs PAs and NPs for hospital coverage. There are 2 physicians in the community who also employ PAs. Hospital bylaws do not permit advance practice providers admit patients; only physicians. The state does allow the APPs to admit under scope of practice.

Is this permissible practice for Moser to prohibit the APs from admitting patient?

- Yes
- No
- Do not know

Patient Admission C0998

- CMS requires Medicare and Medicaid patients be under the care of a MD/DO **IF**
  - Patient has a medical or psych problems outside of the scope of an advanced practice provider
- Admitting privileges must be consistent with state law
- Surveyor will look to make sure a MD/DO monitors the care for any medical problem outside their scope of practice

Patient Admission - continued

- Notify physician when Medicare/Medicaid patient admitted by midlevel
  - Patient with medical/psychiatric issue
  - Or – develops during inpatient stay
  - Outside the scope of NP/PA/CNS scope of practice
  - Document patient is under the care of the MD/DO
- If P&P allow mid-level to admit/care for patients
  - And per state law Scope of Practice
  - Must have P&P to ensure patient safety

Review of Care C0999

- Standard: Periodic review of clinical privileges and performance
  - Quality and appropriateness of care
  - NP, CNS, PA – evaluated by MD/DO
- MD/DO
  - Hospital member of the network
  - QIO
  - Appropriate/quality entity in State rural healthcare plan
  - Telemedicine – by hospital member of the network
- Guidance pending

Unified & Integrated NEW

- Added Unified and integrated medical staff for CAH in multi-facility system
- Must be part of a multiple separately certified hospitals, CAHs and/or REH
  - Elects to have unified and integrate medical staff
  - Members hold privileges and voted by majority to accept or opt out
  - Bylaws, rules and regulations describe process for self-governance, appointment, credentialing, privileging oversight, peer review, etc.
  - Policies and procedures take into account each hospitals circumstances



Provision of Services

Tag Nos. C1006 – 1020

Provision of Services

- **Condition:** Provision of services (C-1004)
- Section establishes requirements related to:
  - Patient care policies
  - Required services
  - Services via agreement/arrangements

Sections to Be Covered

- **Patient care policies (C1006)**
- **Scope of services (C1010)**
- **Emergency medical services (C1012)**
- **Referral, medical records & evaluation of services(C1014)**
- **Drugs and biologicals (C1016)**
- **Food and nutrition (C1020)**
- Patient services(C1024,C1026)
- Laboratory(C1028)
- Radiology (C1030)
- Emergency procedures (C1032)
- Services via Agreements/Arrangements (C1034, 1036, 1038, 1040, 1042, 1044)
- Nursing (C1046, 1048, 1049, 1050)
- Rehab (C1052)
- Visitation rights (C1054, 1056, 1058)

Patient Care Policies C1006

- Standard: Patient care policies
- Services provided per appropriate P&P
  - Consistent with applicable state law
  - Requires services per written policies
- Surveyor will:
  - Review the policies on healthcare services provided in the CAH
  - Observe staff delivering care to the patient
  - If identify practices inconsistent with State law will refer to State authorities

Development of Policies C1008

- Developed with advice of professional staff
  - One or more: MD and PA – NP – CNS
  - If no non-physician practitioners – need not obtain an outside non-physician to serve on the group
- Reviewed every 2 years
  - Recommends changes if needed
- Final decision on content made by governing body
- If recommendations rejected
  - Governing body must include rationale

Scope of Services C1010

- P&P must include
  - Description services provided directly or via contract
- Examples:
  - "Taking complete medical histories – providing complete H&P – laboratory testing – radiology testing –
  - "Arrangements made with Hospital X to provide (the following services)…."

Emergency Medical Services C1012

- Need P&P for emergency medical services
- Surveyor will verify policies:
  - How hospital provides 24/7 emergency care to patients
  - Equipment, supplies, medications, and blood available on site
  - How CAH coordinate with local EMS
  - Type of staff are available to provide care

Guidelines: Medical Management C1014

- When medical consultation or referral is needed
- Maintaining medical records
- Procedure for periodic review and evaluation of the services provided at the CAH
  - General instructions/protocols to medically manage problems commonly seen

APPs & Medical Management

- As mid-levels play large role in patient care at CAH policies must address:
  - Scope of medical acts/procedures may be done by PA, CNS, or NP
  - When the physician is consulted
  - When to refer patient to physician or outside the CAH

Oversight Nurse Midwives

- September memo* reinforced CMS's commitment in providing access and quality care for mothers and infants (see slide 152)
- Critical Access hospitals
  - Must still provide oversight for all inpatients
    - Including non-Medicare patients
  - Must periodically review and sign records all inpatients cared for by advance practice providers

Supervision Clarification

- For CAHs – recognized no authority to remove physician oversight requirements for inpatients
  - Is a statutory requirement
  - Physician oversight requirement for outpatients only applicable if required by State law

Emergency Services Readiness

- Must be adequate provision and protocols to meet emergency needs
  - Protocols – consist with nationally recognized and evidence-based guidelines for care of patients with emergency conditions
    - Including OB emergencies
    - Complications
    - Post delivery complications



Readiness – cont'd

- Staff training – applicable staff trained on protocols and provisions
  - Governing body identify who must complete
  - Must document in personnel records and staff demonstrate knowledge
  - Must use findings from QAPI to inform staff training needs, revisions or updates on ongoing basis



Drugs and Biologicals

Tag Nos. C1016 – 1018

Drugs & Biologicals P&P C1016

- Policies must include rules:
  - For storage – handling – dispensing - administration
  - Storage area administered per acceptable standards of practice
  - Rules that current and accurate records kept for Scheduled drugs
    - Receipt
    - Disposition
  - Outdated, mislabeled, or otherwise unusable drugs are not available for patient use

Requirements

- Consistent with standards or guidelines for pharmaceutical services and medication administration
  - I.e., USP, ASHP, ISMP, Infusion Nurses Society, IHI, and National Coordinating Council
- Consistent with state and federal law
- Others include:
  - ASHP Foundation (American Society of Healthcare System Pharmacist Foundation) – American Nurses Association (ANA) – American Pharmacy Association (APA), APIC, CDC, etc..

Responsibility for Pharmacy Services

- P&Ps must identify the qualifications for and designation of pharmacy director
- Duties:
  - Ensure adherence to State laws
    - Who can perform pharmacy services
    - Supervision of the pharmacy staff
  - Ensure adherence to acceptable standards used in developing P&P
    - Note: Can cite as references in the P&Ps

Storage & Environmental Conditions

- Storage of drugs/biologicals including location of:
  - Storage areas
  - Medication carts
  - Dispensing machines
- Proper environmental conditions
  - Follow manufacturer's recommendations
    - I.e.: keep refrigerated – room temperature – out of light, etc..



Security

- Security
  - P&P must be consistent with State and Federal law re: who authorized to access pharmacy or drug storage areas
    - Housekeeping, security or maintenance are usually not given unsupervised access
  - If kept in private office - patients and visitors not allowed in without supervision



"Secure Area"

- "Secure area" restricted to authorized personnel
  - Given flexibility in non-controlled drugs
    - Not required to be locked when setting up for a procedure
  - Lock when area not staffed – evenings, weekends
  - Covers controlled and non-controlled substances



Security & Monitoring of Carts

- Carts must be secure when not in use
  - Medication carts
  - Anesthesia carts
  - Epidural carts
  - Non-automated medication carts with medications
- Must have P&P
  - Whether locked or unlocked
  - If unlocked- staff must be close by and directly monitoring the cart as when passing medications

Handling Drugs & Biologicals

- "Handling" includes mixing or reconstituting
  - Done per manufacturer's recommendations
  - Includes compounding or admixing of sterile IVs or other drugs
- Only pharmacy can reconstitute, mix, or compound a drug except:
  - In an emergency
  - If not feasible – i.e., product's stability is short

Compounding

- Compounded drugs used or dispensed
  - Must be prepared in a manner consistent with acceptable principles
  - For sterile and non-sterile compounding
  - Prevent microbial contamination and bacterial toxins for compounds intended to be sterile

Pharmacy Responsibilities – Compounding

- Must demonstrate:
  - How it assures all sterile and non-sterile compounded drugs are prepared are pursuant to SOC
  - All compounded forms must be sterile
    - Wound irrigations – eye drops and ointments – injections – infusions – nasal inhalation – etc..



Drug Quality & Security Act - DSQA

- Has sections related to compounding
- "Outsourcing facility"
  - Elected to register and comply with entire section 503B of the FDCA
  - Plus – other requirements such as the FDA's current good manufacturing practice (CGMP)
  - Will be inspected by the FDA according to risk-based schedule
  - Must meet certain other conditions including reporting adverse drug events to the FDA*

*See appendix for resources

Compounding ***Pharmacy***

- If use compounding pharmacy vs manufacturer/ registered outsourcing facility – must
  - Demonstrate medicine received was prepared in accordance with acceptable principles
  - Contract with the vendor - ensure have access to their quality data verifying their compliance with USP standards
  - Document when you obtain and review this data

ISMP & ASHP: Sterile Compounding

- ISMP Guidelines published in 2013*
  - Safe preparation of CSP or compounded sterile preparations (Revised in 2016)
  - Goal: provide procedures and safe practices for reducing errors in CSP preparation
  - Addressed drug storage, compounding, labeling, and staff management
- ASHP issued guidelines* on contracting for sterile compounding services
  - Suggested contract language

* See appendix for resources

Dispensing Drugs and Biologicals

- Comply with state laws re: qualifications of staff
- Dispensed timely
- Sufficient staff – accurate/timely medication delivery
- System to ensure order
  - Get to the pharmacy promptly
  - Available when needed
- Concerns or questions should be clarified with the prescriber before dispensing

Question

Miller CAH utilizes a unit dose system with strict access limitations – only the shift charge nurse or pharmacist on duty. At times, this results in delays in medication administration up to 30 minutes.

Might his result in a citation for Miller?

- Yes – medications must be readily available
- No – 30 minutes is not that long of time
- Not sure

Dispensing

- Can use unit dose or floor stock system
  - Automated dispensing cabinets are secure option
- P&P re: who can access medications after hours (night cabinet standard)
- P&Ps: ("Blue Box")
  - "Do not use" abbreviations*
  - High alert list
  - Quantities dispensed to minimize diversion
  - Limit overrides

For Information Only – Not Required/Not to be Cited

In addition to the required pharmacy policies and procedures above, a well-designed pharmacy service would have policies and procedures addressing medication safety practices such as:

- *Implementation of a do-not-use abbreviation list. CAHs may wish to refer to lists offered by the Institute for Safe Medication Practices (http://www.ismp.org/tools/errorproneabbreviations.pdf) or The Joint Commission (http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf) ;*

- *A high alert drug list. CAHs may wish to refer to a high alert drug list offered by the Institute for Safe Medication Practices (https://www.ismp.org/tools/institutionalhighAlert.asp);*

- *For specific high alert medications designated by the CAH, having two health professionals independently check doses CAHs may wish to refer to guidance from the Institute for Safe Medication Practices concerning appropriate use of double-checks (http://www.ismp.org/Newsletters/acutecare/showarticle.aspx?id=51);*

- *Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;*

- *Whenever possible, medications are dispensed in the most ready to administer form available from the manufacturer or, if feasible, in unit doses that have been repackaged by the pharmacy;*

- *The CAH consistently uses the same dose packaging system, or, if a different system is used, provides education about the use of the dose packaging system; and*

Controlled and Routine Medications

- Keep records – receipt, disposition and use
  - Five schedules of controlled substances – I to V
  - Locked storage when not in use
  - Reconcile any discrepancies in the counts
- Ensure outdated, mislabeled, unusable medication not used
- Must have pharmacy labeling, inspection, and inventory management
- Do not use past beyond use date
  - P&P to determine BUD date if not marked

Do Not Use Abbreviations ISMP

Institute for Safe Medication Practices

ISMP's List of *Error-Prone Abbreviations, Symbols,* and *Dose Designations*

The abbreviations, symbols, and dose designations found in this table have been reported to ISMP through the ISMP National Medication Errors Reporting Program (ISMP MERP) as being frequently misinterpreted and involved in harmful medication errors. They should **NEVER** be used when communicating medical information. This includes internal communications, telephone/verbal prescriptions, computer-generated labels, labels for drug storage bins, medication administration records, as well as pharmacy and prescriber computer order entry screens.

Abbreviations	Intended Meaning	Misinterpretation	Correction
µg	Microgram	Mistaken as "mg"	Use "mcg"
AD, AS, AU	Right ear, left ear, each ear	Mistaken as OD, OS, OU (right eye, left eye, each eye)	Use "right ear," "left ear," or "each ear"
OD, OS, OU	Right eye, left eye, each eye	Mistaken as AD, AS, AU (right ear, left ear, each ear)	Use "right eye," "left eye," or "each eye"
BT	Bedtime	Mistaken as "BID" (twice daily)	Use "bedtime"
cc	Cubic centimeters	Mistaken as "u" (units)	Use "mL"
D/C	Discharge or discontinue	Premature discontinuation of medications if D/C (intended to mean "discharge") has been misinterpreted as "discontinued" when followed by a list of discharge medications	Use "discharge" and "discontinue"
IJ	Injection	Mistaken as "IV" or "intrajugular"	Use "injection"
IN	Intranasal	Mistaken as "IM" or "IV"	Use "intranasal" or "NAS"
HS hs	Half-strength At bedtime, hours of sleep	Mistaken as bedtime Mistaken as half-strength	Use "half-strength" or "bedtime"
IU**	International unit	Mistaken as IV (intravenous) or 10 (ten)	Use "units"
o.d. or OD	Once daily	Mistaken as "right eye" (OD-oculus dexter), leading to oral liquid medications administered in the eye	Use "daily"
OJ	Orange juice	Mistaken as OD or OS (right or left eye); drugs meant to be diluted in orange juice may be given in the eye	Use "orange juice"
Per os	By mouth, orally	The "os" can be mistaken as "left eye" (OS-oculus sinister)	Use "PO," "by mouth," or "orally"

Labeling

- Each individual drug must be labeled
  - Name
  - Strength of drug
  - Lot and control number
  - Expiration date
- Open multidose vial
  - Expiration date of 28 days on the label
  - Unless otherwise specified by manufacturer



Reporting Errors

- Must have a system for reporting ADEs and errors
  - Educate staff
- Pharmacy to assess
  - If problems in pharmacy caused or contribute to these
- Hospital must take action to address identified issues
  - QAPI

Surveyor Questions & Actions

- Nursing
  - Medications dispensed in a timely manner
  - If late – surveyor will investigate
- Pharmacy
  - Professional principles pharmacy using
- Will ensure drugs are secure
- Will verify only pharmacist/authorized person compound, label and dispense
  - Some states prohibit pharmacy tech from completing

Surveyor Duties

- Ensure facility has a process to follow up on ADE and medication errors
- Will determine if CAH obtains compounded drugs from external source not FDA registered
  - Does the facility evaluate and monitor adherence to safe principles
  - Ask for example of when the BUD had to be determined for a compounded sterile medication based on P&P
- Long survey procedure for this tag number

Reporting ADR & Errors C1018

- Procedures for reporting adverse drug events (ADEs) and medication errors
- Staff must report events/errors
  - Attend to patient and report to QAPI
  - Need P&P and ensure staff aware
- Need definition of each
  - CMS mentions National Coordinating Council Medication Error Reporting and Prevention

Medication Administration Error

- Preventable event
- May cause or lead to inappropriate medication use or patient harm
- While in control of HCP, patient or consumer
- Related to
  - Professional practice
  - Healthcare products
  - Procedures
  - Systems including

Adverse Drug Reaction

- Unexpected, unintended, undesired or excessive response to a drug
  - D/C drug
  - Changing therapy
  - Modifying dose
  - Prolongs stay
  - Necessitates supporting treatment
  - Significantly complicates diagnosis
  - Negatively affects prognosis
  - Results in temporary/permanent harm, disability, death

Patient Care

- ADR/errors that reach the patient must be reported to the practitioner
  - Report made immediately if causes harm
  - If harm is not known – must report immediately
  - If no harm – can notify practitioner in the morning
- Document:
  - Error
  - Notification of practitioner

Quality Assurance/Improvement Reporting

- Reduction of errors/ADR may be facilitated by effective reporting
  - Assess vulnerabilities in process
  - Implement corrective actions
- Must educate staff on errors/ADRs to facilitate reporting & how to report
  - Near misses
  - I.e., incident report sent to pharmacy, nursing, risk management, and then into the QAPI program
  - Can do RCA, FMEA, or QAPI review

Other Actions

- Encourage non-punitive approach – focus on system issues
  - Do not rely on incident reports only
- Take other steps to identify errors and ADRs
  - Trigger drug analysis
  - Observe medication passes
  - Medication usage evaluations for **high alert drugs** etc..
- Encourages reporting to the FDA MedWatch Program and ISMP MER system*

*See appendix

Non-Punitive Environment

- Studies: punitive environment results in errors not being reported
  - Most of serious errors made by long term employees or physicians with unblemished records
  - System led to the error
- Need to change the environment or culture
- Important to have a non-punitive environment
- Balance with Just Culture



Survey Procedure C1018

- Ensure nursing staff know what to do if there is a medication error or ADR
- Ask nursing to provide an example of what they would do if error or ADR
- Review records of errors/ADR – immediately reported and documented
- Ensure hospital has system for reporting to QAPI
- Make sure staff trained in reporting expectations

High Alert How to Guide IHI



v03
10/01/2008

PROTECTING 5 Million lives FROM HARM IHI.org

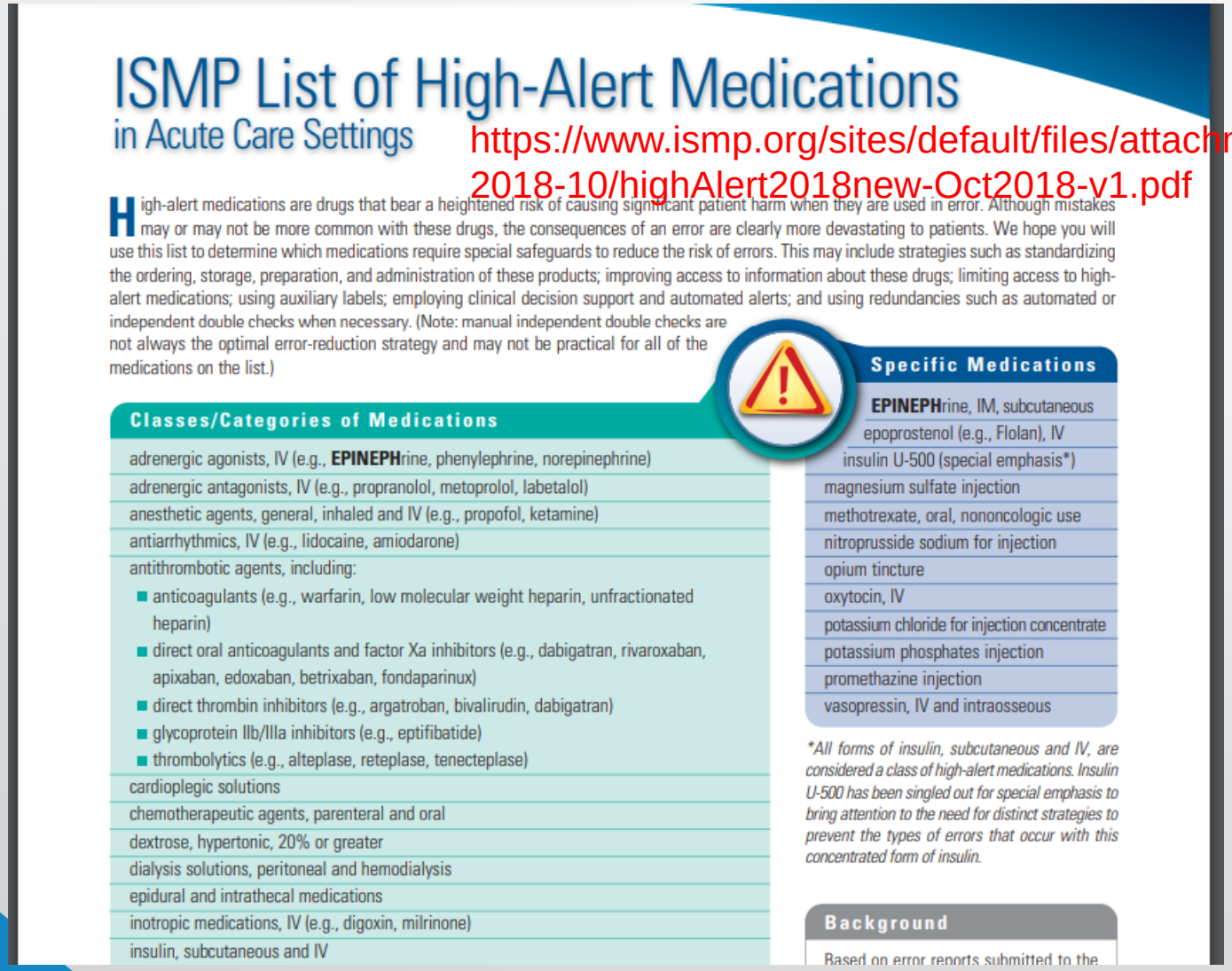
Getting Started Kit:
Prevent Harm from High-Alert Medications

How-to Guide

A national initiative led by IHI, the 5 Million Lives Campaign aims to dramatically improve the quality of American health care by protecting patients from five million incidents of medical harm between December 2006 and December 2008. The How-to

www.ihi.org/NR/rdonlyres/8B2475CD-56C7-4D9B-B359-801F3CC3A8D5/0/HighAlertMedicationsHowToGuide.doc

ISMP List of High Alert Medication



ISMP List of High-Alert Medications
in Acute Care Settings

https://www.ismp.org/sites/default/files/attachments/2018-10/highAlert2018new-Oct2018-v1.pdf

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients. We hope you will use this list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies such as standardizing the ordering, storage, preparation, and administration of these products; improving access to information about these drugs; limiting access to high-alert medications; using auxiliary labels; employing clinical decision support and automated alerts; and using redundancies such as automated or independent double checks when necessary. (Note: manual independent double checks are not always the optimal error-reduction strategy and may not be practical for all of the medications on the list.)

Classes/Categories of Medications

- adrenergic agonists, IV (e.g., **EPINEPH**rine, phenylephrine, norepinephrine)
- adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)
- anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)
- antiarrhythmics, IV (e.g., lidocaine, amiodarone)
- antithrombotic agents, including:
  - anticoagulants (e.g., warfarin, low molecular weight heparin, unfractionated heparin)
  - direct oral anticoagulants and factor Xa inhibitors (e.g., dabigatran, rivaroxaban, apixaban, edoxaban, betrixaban, fondaparinux)
  - direct thrombin inhibitors (e.g., argatroban, bivalirudin, dabigatran)
  - glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide)
  - thrombolytics (e.g., alteplase, reteplase, tenecteplase)
- cardioplegic solutions
- chemotherapeutic agents, parenteral and oral
- dextrose, hypertonic, 20% or greater
- dialysis solutions, peritoneal and hemodialysis
- epidural and intrathecal medications
- inotropic medications, IV (e.g., digoxin, milrinone)
- insulin, subcutaneous and IV

Specific Medications

- **EPINEPH**rine, IM, subcutaneous
- epoprostenol (e.g., Flolan), IV
- insulin U-500 (special emphasis*)
- magnesium sulfate injection
- methotrexate, oral, nononcologic use
- nitroprusside sodium for injection
- opium tincture
- oxytocin, IV
- potassium chloride for injection concentrate
- potassium phosphates injection
- promethazine injection
- vasopressin, IV and intraosseous

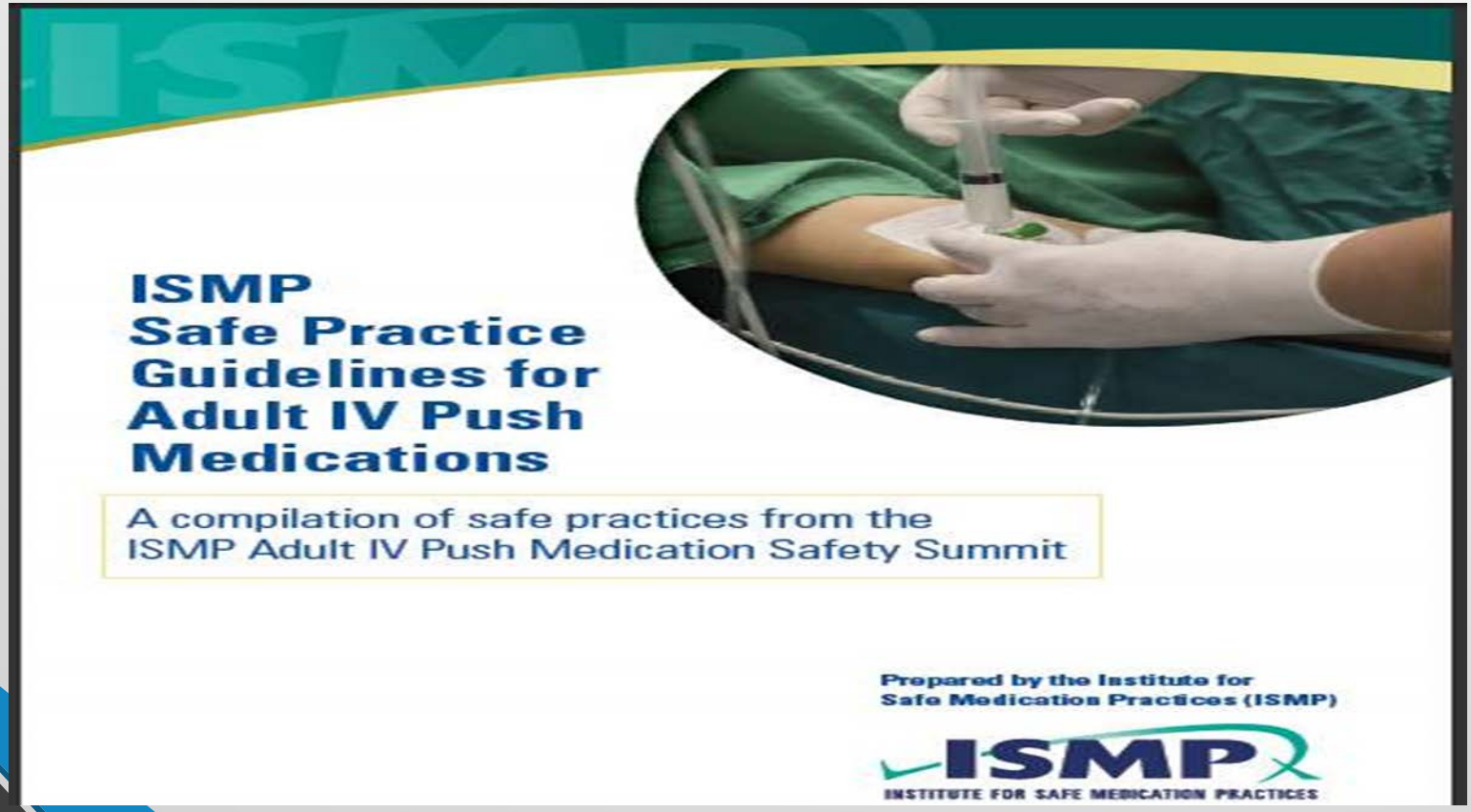
**All forms of insulin, subcutaneous and IV, are considered a class of high-alert medications. Insulin U-500 has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent the types of errors that occur with this concentrated form of insulin.*

Background

Based on error reports submitted to the

Importance of ISMP IV Push Guidelines

- CMS requires following of standards of care
  - Specifically mentions ISMP



Safe Injection Practices

- Must ensure staff follow SOP to prevent HAI related to medication preparation including CSP
  - Assessed under infection control section
- Compounded sterile preparations (CSP) can cause HAI if proper precautions not followed such as USP standards
  - Nurses may prepare sterile medication for immediate use





Dietary Standards

Tag Nos. C1020 - 1022

Dietary C1020

- Nutritional needs of inpatients met per recognized dietary practices
- All diets ordered by practitioner responsible for care or:
  - Qualified dietitian (new) OR
  - Qualified nutrition professional (new)
  - Authorized by medical staff and per state law (new)
- Survey procedures and interpretive guidelines are pending

Previous Interpretive Guidelines

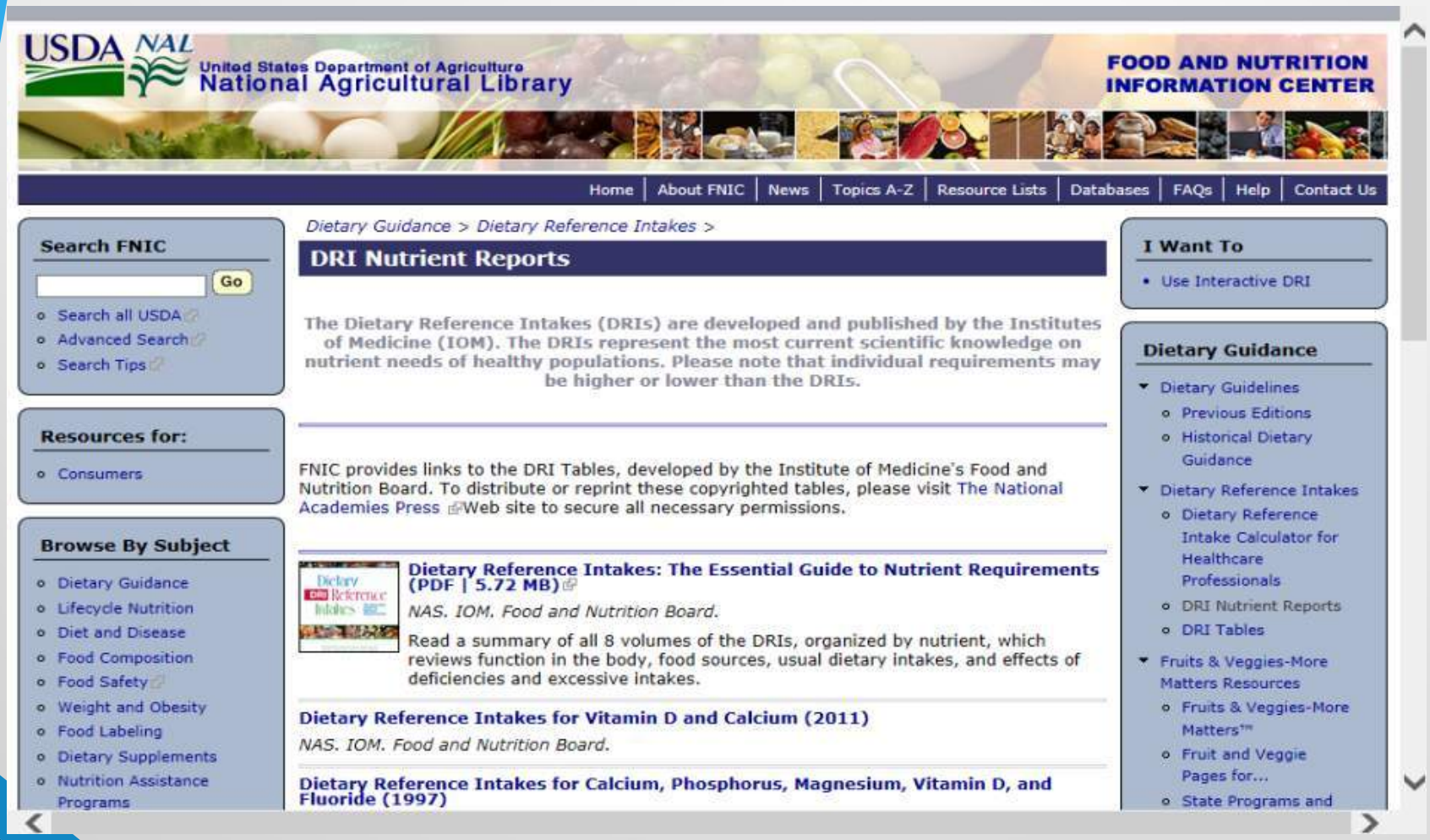
- Provided in the appendix as reference only
  - Final interpretive guidelines pending
- CAH is not required to prepare meals itself
- Can obtain meals under contract
- Must be staffed to ensure that the nutritional needs of the patients are met
  - Patient assessment
  - Order present

Policies Reviewed C1022

- Policies are reviewed at least biennially
  - By a group of professional personal – NP, PA, CNS, MD/DO
- Interpretive guidelines and survey procedure pending



IOM Dietary Reference Intake



http://fnic.nal.usda.gov/dietary-guidance/dietary-reference-intakes/dri-nutrient-reports

Dietary Reference Intakes (DRIs): Estimated Average Requirements

Food and Nutrition Board, Institute of Medicine, National Academies

Life Stage Group	Calcium (mg/d)	CHO (g/kg/d)	Protein (g/d)	Vit A (μg/d)[a]	Vit C (mg/d)	Vit D (μg/d)	Vit E (mg/d)[b]	Thiamin (mg/d)	Ribo-flavin (mg/d)	Niacin (mg/d)[c]	Vit B_6 (mg/d)	Folate (μg/d)[d]	Vit B_{12} (μg/d)	Copper (μg/d)	Iodine (μg/d)	Iron (mg/d)	Magnes-ium (mg/d)	Molyb-denum (μg/d)	Phos-phorus (mg/d)	Sele-nium (μg/d)	Zinc (mg/
Infants																					
0 to 6 mo																					
6 to 12 mo			1.0													6.9					2.5
Children																					
1–3 y	500	100	0.87	210	13	10	5	0.4	0.4	5	0.4	120	0.7	260	65	3.0	65	13	380	17	2.5
4–8 y	800	100	0.76	275	22	10	6	0.5	0.5	6	0.5	160	1.0	340	65	4.1	110	17	405	23	4.0
Males																					
9–13 y	1,100	100	0.76	445	39	10	9	0.7	0.8	9	0.8	250	1.5	540	73	5.9	200	26	1,055	35	7.0
14–18 y	1,100	100	0.73	630	63	10	12	1.0	1.1	12	1.1	330	2.0	685	95	7.7	340	33	1,055	45	8.5
19–30 y	800	100	0.66	625	75	10	12	1.0	1.1	12	1.1	320	2.0	700	95	6	330	34	580	45	9.4
31–50 y	800	100	0.66	625	75	10	12	1.0	1.1	12	1.1	320	2.0	700	95	6	350	34	580	45	9.4
51–70 y	800	100	0.66	625	75	10	12	1.0	1.1	12	1.4	320	2.0	700	95	6	350	34	580	45	9.4
> 70 y	1,000	100	0.66	625	75	10	12	1.0	1.1	12	1.4	320	2.0	700	95	6	350	34	580	45	9.4
Females																					
9–13 y	1,100	100	0.76	420	39	10	9	0.7	0.8	9	0.8	250	1.5	540	73	5.7	200	26	1,055	35	7.0
14–18 y	1,100	100	0.71	485	56	10	12	0.9	0.9	11	1.0	330	2.0	685	95	7.9	300	33	1,055	45	7.3
19–30 y	800	100	0.66	500	60	10	12	0.9	0.9	11	1.1	320	2.0	700	95	8.1	255	34	580	45	6.8
31–50 y	800	100	0.66	500	60	10	12	0.9	0.9	11	1.1	320	2.0	700	95	8.1	265	34	580	45	6.8
51–70 y	1,000	100	0.66	500	60	10	12	0.9	0.9	11	1.3	320	2.0	700	95	5	265	34	580	45	6.8
> 70 y	1,000	100	0.66	500	60	10	12	0.9	0.9	11	1.3	320	2.0	700	95	5	265	34	580	45	6.8
Pregnancy																					
14–18 y	1,000	135	0.88	530	66	10	12	1.2	1.2	14	1.6	520	2.2	785	160	23	335	40	1,055	49	10.5
19–30 y	800	135	0.88	550	70	10	12	1.2	1.2	14	1.6	520	2.2	800	160	22	290	40	580	49	9.5
31–50 y	800	135	0.88	550	70	10	12	1.2	1.2	14	1.6	520	2.2	800	160	22	300	40	580	49	9.5
Lactation																					
14–18 y	1,000	160	1.05	885	96	10	16	1.2	1.3	13	1.7	450	2.4	985	209	7	300	35	1,055	59	10.9
19–30 y	800	160	1.05	900	100	10	16	1.2	1.3	13	1.7	450	2.4	1,000	209	6.5	255	36	580	59	10.4
31–50 y	800	160	1.05	900	100	10	16	1.2	1.3	13	1.7	450	2.4	1,000	209	6.5	265	36	580	59	10.4

NOTE: An Estimated Average Requirement (EAR) is the average daily nutrient intake level estimated to meet the requirements of half of the healthy individuals in a group. EARs have not been established for vitamin K, pantothenic acid, biotin, choline, chromium, fluoride, manganese, or other nutrients not yet evaluated via the DRI process.

Summation Event

CAH contracts with TE – Telemedicine Entity – for pulmonology support in the ICU. TE is based in another state but provides services in multiple states. All physicians are on staff at a teaching institution in the company's home state and granted privileges at CAH with Board approval.

Patient Z is inpatient the step-down unit but experiences a respiratory arrest. TE is contacted for assistance and support in managing the event but is pronounced deceased before she can be admitted to ICU.

Summation Event – (cont.)

The contract between CAH and TE is silent on telemedicine services provided outside the ICU. The state appears 4 days later to investigate the event. What, if any, citations/deficiencies might CAH receive?

- None –TE was just trying to help
- Contract – no provision for such care; should have been considered
- Failure to adequately provide telemedicine services
- Others?

Thank You



- Laura A. Dixon, Esq.
- BS, JD, RN, CPHRM
- President, Healthcare Risk Education and Consulting, LLC
- ldesq@comcast.net

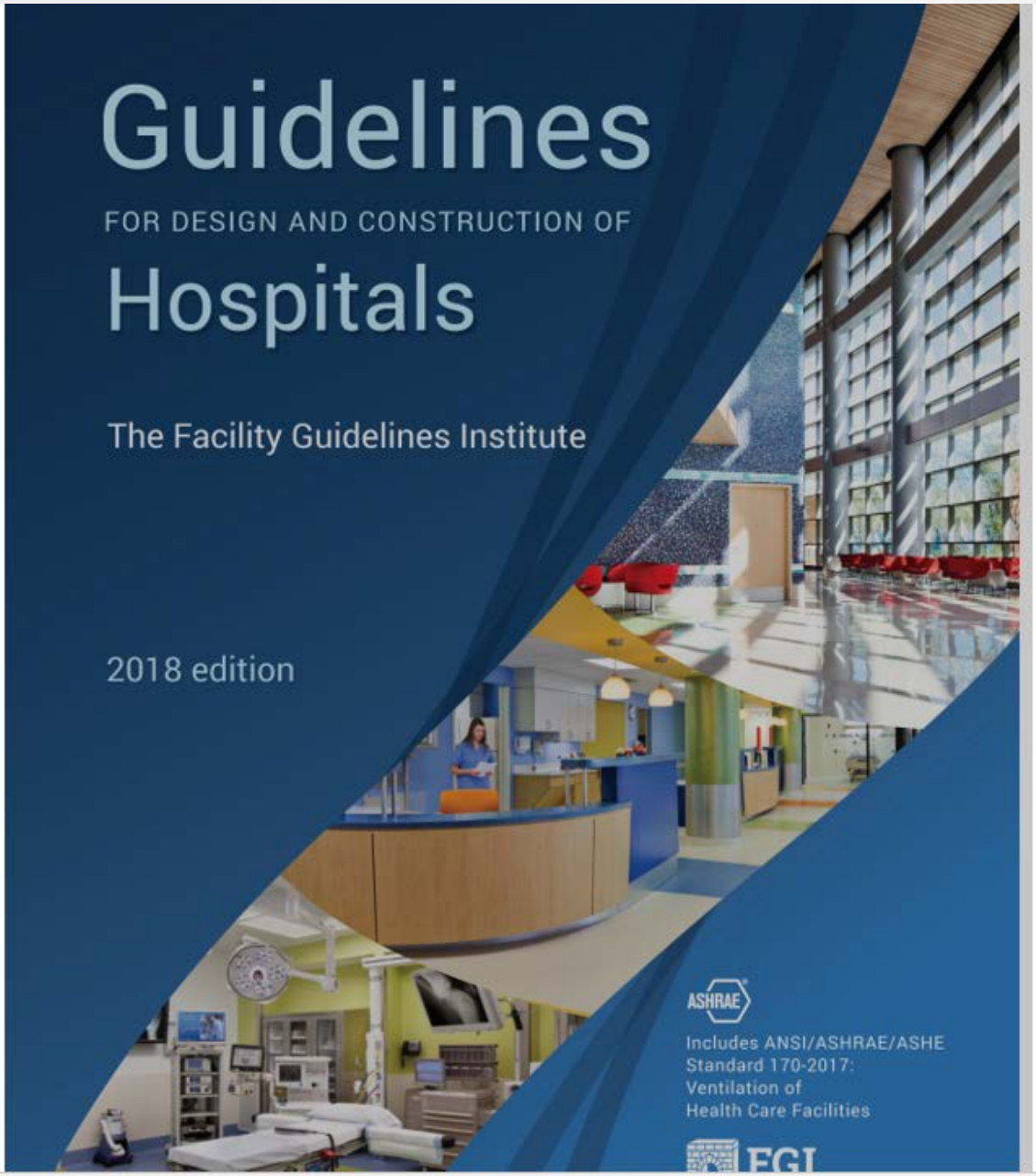
144

Appendix

Resources

and

Internet Links


Guidelines
FOR DESIGN AND CONSTRUCTION OF
Hospitals
The Facility Guidelines Institute
2018 edition
ASHRAE
Includes ANSI/ASHRAE/ASHE
Standard 170-2017:
Ventilation of
Health Care Facilities
FGI

Equipment Maintenance

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 14-07-Hospital

DATE: **December 20, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Hospital Equipment Maintenance Requirements

Memorandum Summary

- ***S&C 12-07-Hospital Superceded:*** We are updating previously provided guidance to clarify:
  - Hospital facilities, supplies and equipment must be maintained to ensure an acceptable level of safety and quality.
  - A hospital may adjust its maintenance, inspection, and testing frequency and activities for facility and medical equipment from what is recommended by the manufacturer, based on a risk-based assessment by qualified personnel, unless:
    - Other Federal or state law; or hospital Conditions of Participation (CoPs) require adherence to manufacturer's recommendations and/or set specific requirements. For example, all imaging/radiologic equipment must be maintained per manufacturer's recommendations; or
    - The equipment is a medical laser device; or
    - New equipment without a sufficient amount of maintenance history has been

Equipment Memo

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 14-41-CAH

DATE: **August 8, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Critical Access Hospital (CAH) Equipment Maintenance Requirements

Memorandum Summary

- In accordance with 42 CFR 485.623(b)(1), CAHs are required to maintain all essential mechanical, electrical and patient-care equipment in safe operating condition.
  - A CAH may adjust its maintenance, inspection, and testing frequency and activities for facility and medical equipment from what is recommended by the manufacturer, based on a risk-based assessment, unless:
    - Other Federal or state law, or CAH Conditions of Participation (CoPs) require adherence to manufacturer's recommendations and/or set specific requirements. For example, the National Fire Protection Association (NFPA) Life Safety Code (LSC) requirements incorporated by reference at 42 CFR 485.623(d) have some provisions pertinent to equipment maintenance, and compliance with these requirements is assessed on Federal surveys; or
    - The equipment is imaging/radiologic equipment or a medical laser device; or
    - New equipment without a sufficient amount of maintenance history has been acquired.
- CAHs electing to adjust facility or medical equipment maintenance must develop policies and procedures and maintain documentation supporting their Alternate Equipment

Effects of Lowering Humidity

RELATIVE HUMIDITY LEVELS IN THE OPERATING ROOM
JOINT COMMUNICATION TO HEALTHCARE DELIVERY ORGANIZATIONS
January 2015

This is an important communication to the multiple stakeholders in healthcare whose work touches sterile supplies and electro-medical equipment used in delivering care to patients. The subject is about how relative humidity (RH) levels lower than 30% can impact the integrity and functionality of some of these products, with a special emphasis on RH levels in the operating room (OR). The following professional organizations have collaborated in the development of this communication: Ambulatory Surgery Center Association (ASCA), American College of Clinical Engineering (ACCE), American Hospital Association (AHA), American Society for Healthcare Engineering (ASHE), American Society of Anesthesiologists (ASA), American Society of Heating, Refrigeration and Air Conditioning Engineers (ASHRAE), Association for Healthcare Resource & Materials Management (AHRMM), Association for the Advancement of Medical Instrumentation (AAMI), Association of periOperative Registered Nurses (AORN), Association of Surgical Technologists (AST), Health Industry Distributors Association (HIDA), and the International Association of Healthcare Central Service Materials Management (IAHCSMM).[1]

Joint Commission and ASHRAE

- Joint effort with multiple organizations on humidity in OR
- RH lower than 30% can impact integrity and functionality of supplies and electro-medical equipment
- Was lowered to 20 – 30% upon request of multiple organizations
  - Upper limit 60%

https://www.aorn.org

Impact of Lowering the Humidity

American Hospital Association®

ASHE American Society for Healthcare Engineering, A personal membership group of the American Hospital Association

AHRMM Association for Healthcare Resource & Materials Management, Advancing the Healthcare Supply Chain, A personal membership group of the American Hospital Association

Quality Advisory

January 21, 2015

01-21-2015 Accessed ; https://www.magnetmail.net/actions/email_web_version.cfm?recipient_id=1331564405&message_id=8663272&user_id=AHA_8&group_id=1105177&jobid=25267573

New Guidance on Humidity Levels in the Operating Room

The Issue

A change in the standards regulating a hospital's physical environment in the operating room (OR) may conflict with the instructions for use on some equipment and supplies routinely used in surgery. To ensure patient safety during surgery, the AHA in collaboration with its personal membership groups, the American Society for Healthcare Engineering (ASHE) and the Association for Healthcare Resource & Materials Management (AHRMM), urge hospitals to examine their humidity levels in the OR and consider the effects on equipment and products used during surgery. This advisory and associated attachments will assist in your assessment.

Background

Many safety codes and standards regulating the health care physical environment now require relative humidity levels in **ORs** (not other areas of the facility) to be at least 20 percent, a change from the 30 percent minimum humidity required by some previous editions of codes. The 20 percent threshold provides hospitals with flexibility during

May 2022 Memo

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-41-ALL
REVISED 06.21.2021
REVISED 05.26.2022

DATE: **September 28, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Guidance related to Emergency Preparedness- Exercise Exemption based on A Facility's Activation of their Emergency Plan

**** Revised to provide additional guidance and clarifications due to the ongoing COVID-19 public health emergency (PHE) ****

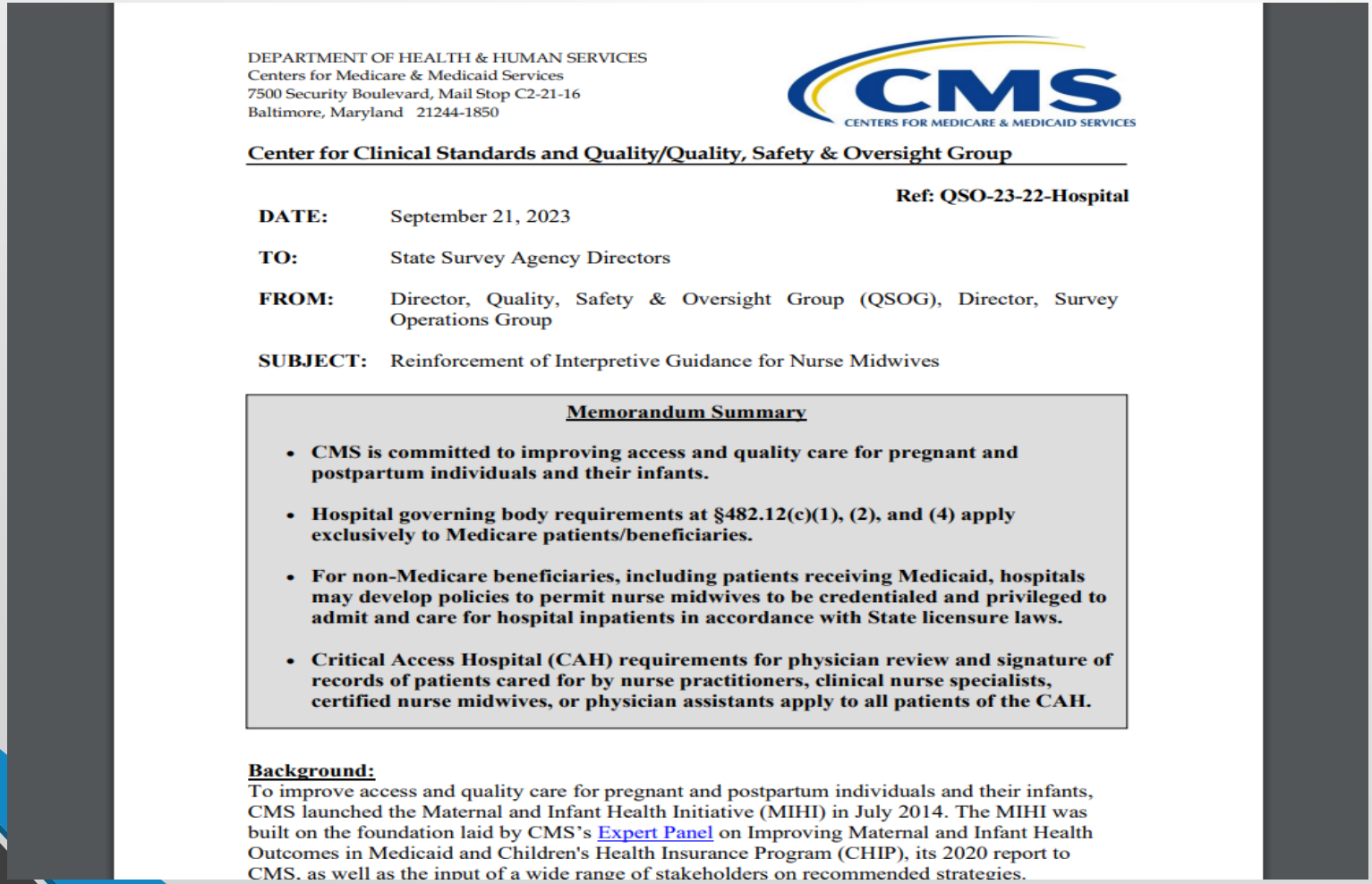
Memorandum Summary

- ***Emergency Preparedness Training and Testing Program Exemption*** - CMS regulations for Emergency Preparedness (EP) require facilities to conduct exercises to test the facility's EP plan to ensure that it works and that staff are trained appropriately about their roles and the facility's processes. During or after an actual emergency, the regulations allow for a one-year exemption from the requirement that the facility perform testing exercises.

- This worksheet presents guidance for surveyors, as well as providers and suppliers, with assessing a facility's compliance with the EP requirements, in light of many of the response activities associated with the COVID-19 Public Health Emergency (PHE).

September 2023 Memo - CNMs

https://www.cms.gov/files/document/qso-23-22-hospital.pdf



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-23-22-Hospital

DATE: September 21, 2023

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG), Director, Survey Operations Group

SUBJECT: Reinforcement of Interpretive Guidance for Nurse Midwives

Memorandum Summary

- **CMS is committed to improving access and quality care for pregnant and postpartum individuals and their infants.**
- **Hospital governing body requirements at §482.12(c)(1), (2), and (4) apply exclusively to Medicare patients/beneficiaries.**
- **For non-Medicare beneficiaries, including patients receiving Medicaid, hospitals may develop policies to permit nurse midwives to be credentialed and privileged to admit and care for hospital inpatients in accordance with State licensure laws.**
- **Critical Access Hospital (CAH) requirements for physician review and signature of records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants apply to all patients of the CAH.**

Background:
To improve access and quality care for pregnant and postpartum individuals and their infants, CMS launched the Maternal and Infant Health Initiative (MIHI) in July 2014. The MIHI was built on the foundation laid by CMS's Expert Panel on Improving Maternal and Infant Health Outcomes in Medicaid and Children's Health Insurance Program (CHIP), its 2020 report to CMS, as well as the input of a wide range of stakeholders on recommended strategies.

TJC's Do Not Use Abbreviation List

Facts about the Official "Do Not Use" List

In 2001, The Joint Commission issued a *Sentinel Event Alert* on the subject of medical abbreviations, and just one year later, its Board of Commissioners approved a National Patient Safety Goal requiring accredited organizations to develop and implement a list of abbreviations not to use. In 2004, The Joint Commission created its "do not use" list of abbreviations (see below) as part of the requirements for meeting that goal. In 2010, NPSG.02.02.01 was integrated into the Information Management standards as elements of performance 2 and 3 under IM.02.02.01.

Currently, this requirement does not apply to preprogrammed health information technology systems (for example, electronic medical records or CPOE systems), but this application remains under consideration for the future. Organizations contemplating introduction or upgrade of such systems should strive to eliminate the use of dangerous abbreviations, acronyms, symbols, and dose designations from the software.

Official "Do Not Use" List[1]

Do Not Use	*Potential Problem*	Use Instead
U, u (unit)	Mistaken for "0" (zero), the number "4" (four) or "cc"	Write "unit"
IU (International Unit)	Mistaken for IV (intravenous) or the number 10 (ten)	Write "International Unit"
Q.D., QD, q.d., qd (daily)	Mistaken for each other	Write "daily"
Q.O.D., QOD, q.o.d, qod (every other day)	Period after the Q mistaken for "I" and the "O" mistaken for "I	Write "every other day"
Trailing zero (X.0 mg)* Lack of leading zero (.X mg)	Decimal point is missed	Write X mg Write 0.X mg
MS	Can mean morphine sulfate or magnesium sulfate	Write "morphine sulfate" Write "magnesium sulfate"
MSO_4 and $MgSO_4$	Confused for one another	

OIG Report on Oversight of Hospital Pharmacies

http://oig.hhs.gov/oei/reports/oei-01-13-00400.pdf

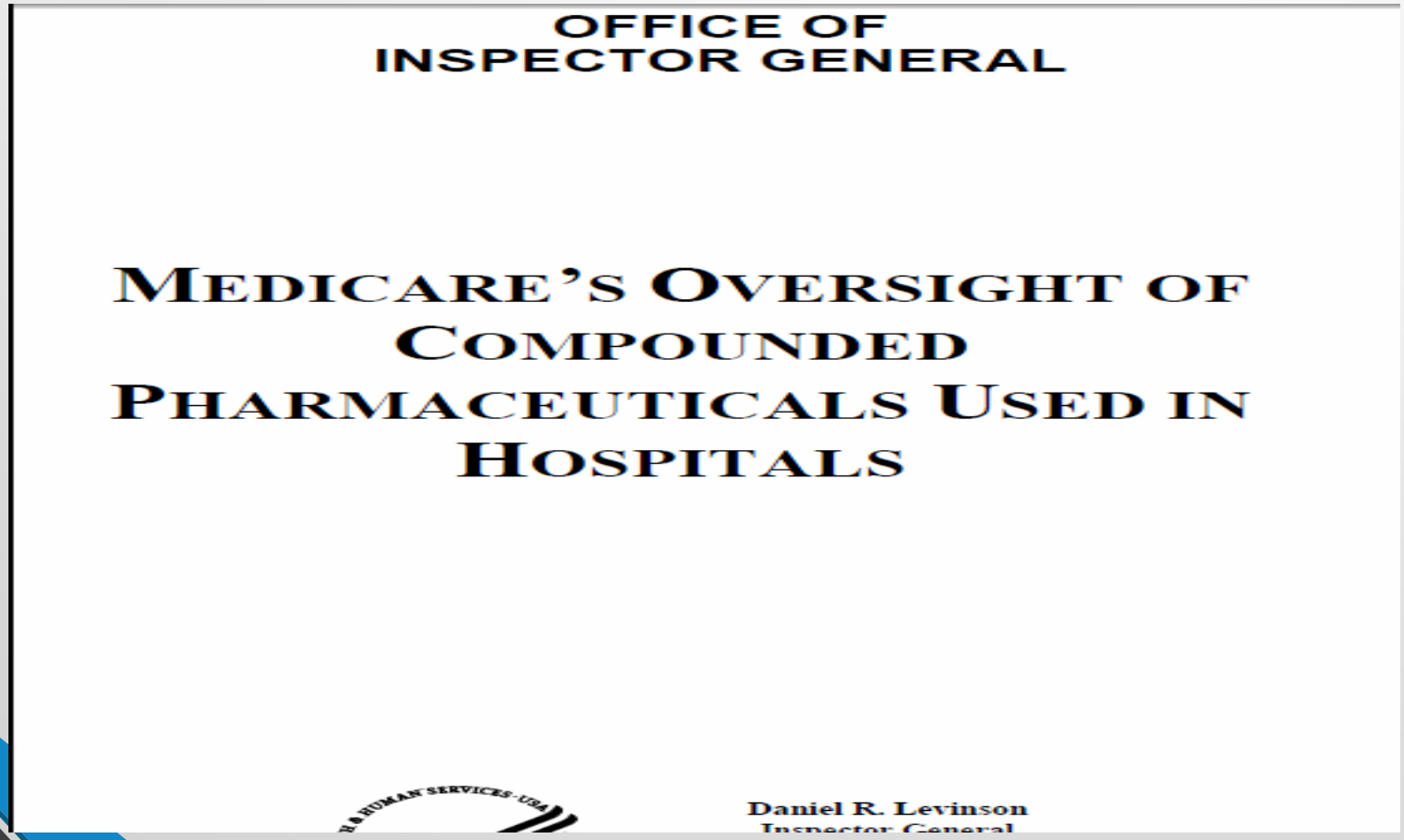
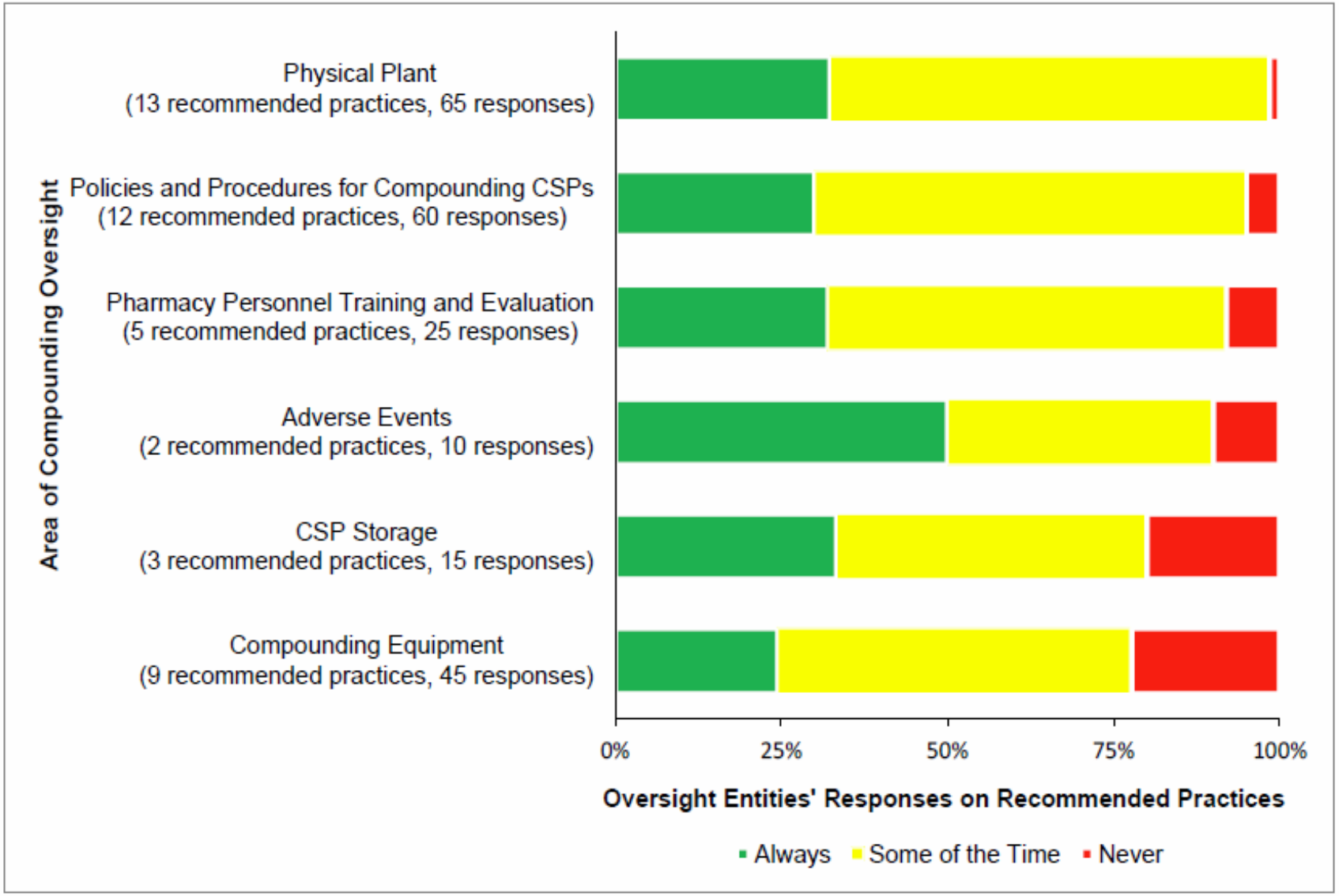


Figure 1: Extent to Which the Five Oversight Entities Incorporate Recommended Practices for Each Area of Compounding Oversight Into Surveys



Source: OIG analysis of responses to questionnaire by CMS and the four accreditors, 2014.

Table A1: Extent to Which Oversight Entity Surveys Incorporate Recommended Practices Related to the Hospital Physical Plant and Environmental Quality

Recommended Practice	Oversight Entities Responding		
	Always	Some of the Time	Never
Do surveyors request a copy of the hospital's pharmacy cleaning logs?	1	4	0
Do surveyors request a copy of the hospital's pharmacy environmental sampling logs?	0	5	0
If the hospital prepares CSPs onsite, do surveyors assess whether the area of preparation is appropriate for all CSP risk levels compounded at the hospital?	2	3	0
If the hospital prepares hazardous CSPs onsite, do surveyors assess the appropriateness of the physical area where hazardous CSPs are compounded?	3	2	0
If the hospital prepares CSPs onsite, do surveyors assess the environmental quality and control in the area of preparation?	3	2	0
If always or some of the time, do surveyors assess the adequacy of the environmental quality and control for each risk level of CSP prepared at the hospital?	2	3	0
If the hospital prepares CSPs onsite, do surveyors review the hospital's written procedures outlining the following:			
Cleaning and disinfecting of the compounding areas?	1	4	0
Personnel hand hygiene and garbing in compounding areas?	3	2	0
Employee aseptic technique in compounding areas?	2	3	0
Environmental sampling in compounding areas?	0	5	0
Facility and engineering control testing and certification in compounding areas?	0	4	1
If the hospital prepares CSPs onsite, do surveyors assess the adequacy of personnel protective equipment for compounding CSPs, including applicable	2	3	0

http://apic.org/Resource_/TinyMceFileManager/Academy/ASC_101_resources/Sterilization/ASHP_Outsourcing_Sterile_Compounding_2010.pdf

ASHP Guidelines on Outsourcing Sterile Compounding Services

Purpose

Health care organizations considering outsourcing sterile compounding services should have a clear understanding of what they want to accomplish. Consideration should include, at the least, an internal needs assessment, a cost analysis, and a careful review of prospective compounding pharmacies. The organization should examine the potential long-term consequences of outsourcing as well as the short-term outcomes expected during a contract's performance period.

The purpose of these guidelines is to provide an overview of factors and processes for health care organizations to consider when exploring outsourcing of pharmacy sterile compounding. The ideas presented in this document could be used for strategic planning with the organization's decision-makers, for drafting contract provisions, for comparing prospective compounding pharmacies, for preparing for contract negotiations, or for evaluating a compounding pharmacy's performance.

This document includes ideas about reasons for outsourcing and reasons for not outsourcing, services available from compounding pharmacies, the outsourcing process and outsourcing arrangements, and evaluation of a compounding pharmacy's performance. The appendix provides a topical list of contract provisions, some of which relate to practices that are the subject of other American Society of Health-System Pharmacy (ASHP) guidelines. Organizations should refer to pertinent ASHP guidelines for additional information on which to base their contract provisions, agreements, and deci-

- Shortage of pharmacy personnel with specific experience and capabilities.

Financial and Cost Control

- Restricted budgets.
- Increased operating costs.
- Increased drug costs.
- Increased emphasis on measuring performance in terms of staffing and costs.

Quality Assurance

- Increased expectations of and pressures from payers, accreditation organizations, and consumer groups to improve the quality of patient care, reduce the incidence of hospital infections, and demonstrate compliance with applicable standards and regulations.

Governmental and Regulatory

- Reductions of federal, state, and local government reimbursement for health care.
- Increased numbers of individuals dependent on federal, state, and local governments for health care.
- Increased federal and state interest in standards for sterile compounding (i.e., *United States Pharmacopeia* [*USP*] chapter 797[4]).

ASHP Guidelines on Outsourcing

www.ashp.org/DocLibrary/BestPractices/MgmtGdlOutsourcingSterileComp.aspx

ASHP Guidelines on Outsourcing Sterile Compounding Services

Purpose

The purpose of these guidelines is to provide an overview of factors and processes for healthcare organizations to consider when contracting with compounding pharmacies or outsourcing facilities to obtain sterile compounding services. These guidelines describe services available from compounding pharmacies or outsourcing facilities, reasons for outsourcing and reasons for not outsourcing, the outsourcing process and outsourcing arrangements, and recommendations for evaluating a contractor's performance. The guidelines also provide a topical list of contract provisions, some of which relate to practices that are the subject of other ASHP guidelines. Organizations should refer to pertinent ASHP guidelines for additional information on which to base their contract provisions, agreements, and decisions.[1-3] The concepts presented in this document could be used for strategic planning with the organization's decision-makers, assisting in assessing the quality of compounded sterile preparations or products, drafting contract provisions, comparing prospective contractors, preparing for contract negotiations, and evaluating contractor performance.

This document addresses representative outsourcing options and contract agreements and is not intended to cover all situations. Managers of pharmacy and healthcare organizations should use their professional judgment about applicability to their own needs and circumstances.

Services Provided by

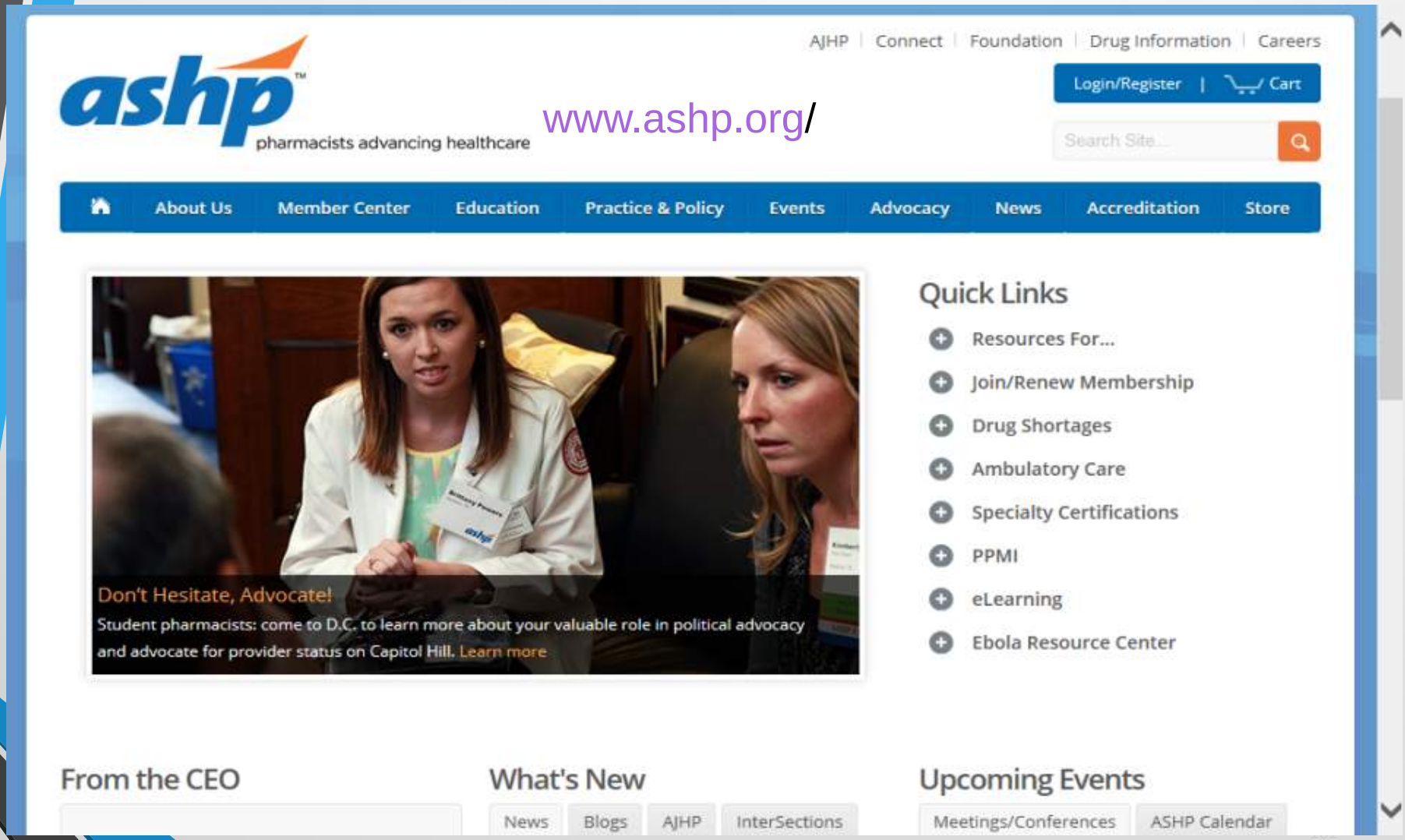
Compounding Pharmacies. Section 503A clarified the FD&C Act for activities described as traditional patient-specific compounding (sometimes now called "503A compounding"). Healthcare organization pharmacies fall into this category, as do other pharmacies that fill prescriptions or medication orders within a prescriber–pharmacist–patient professional relationship. All 503A compounding pharmacies, except those in federal facilities, are regulated by state boards of pharmacy; however, they may also be subject to Food and Drug Administration (FDA) inspection under the agency's authority to enforce section 503A of the FD&C Act. The agency's expectations for compliance are specified in the FDA *Compliance Policy Guide* (CPG) *on Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.*[5] In addition to current regulatory requirements, such as prescriptions or medication orders for compounded preparations and compliance with applicable *United States Pharmacopeia* (*USP*) chapters on compounding (i.e., *USP* chapters 795 and 797),[8,9] inspectors may look for implementation of additional CPG recommendations. The services provided by compounding pharmacies are limited by the existing requirement for individual prescriptions or medication orders and may be further limited by forthcoming regulation of distribution across state lines,[7] state and federal restrictions on office-use preparations, and other limitations of section 503A.

Outsourcing Facilities. Section 503B outsourcing facilities

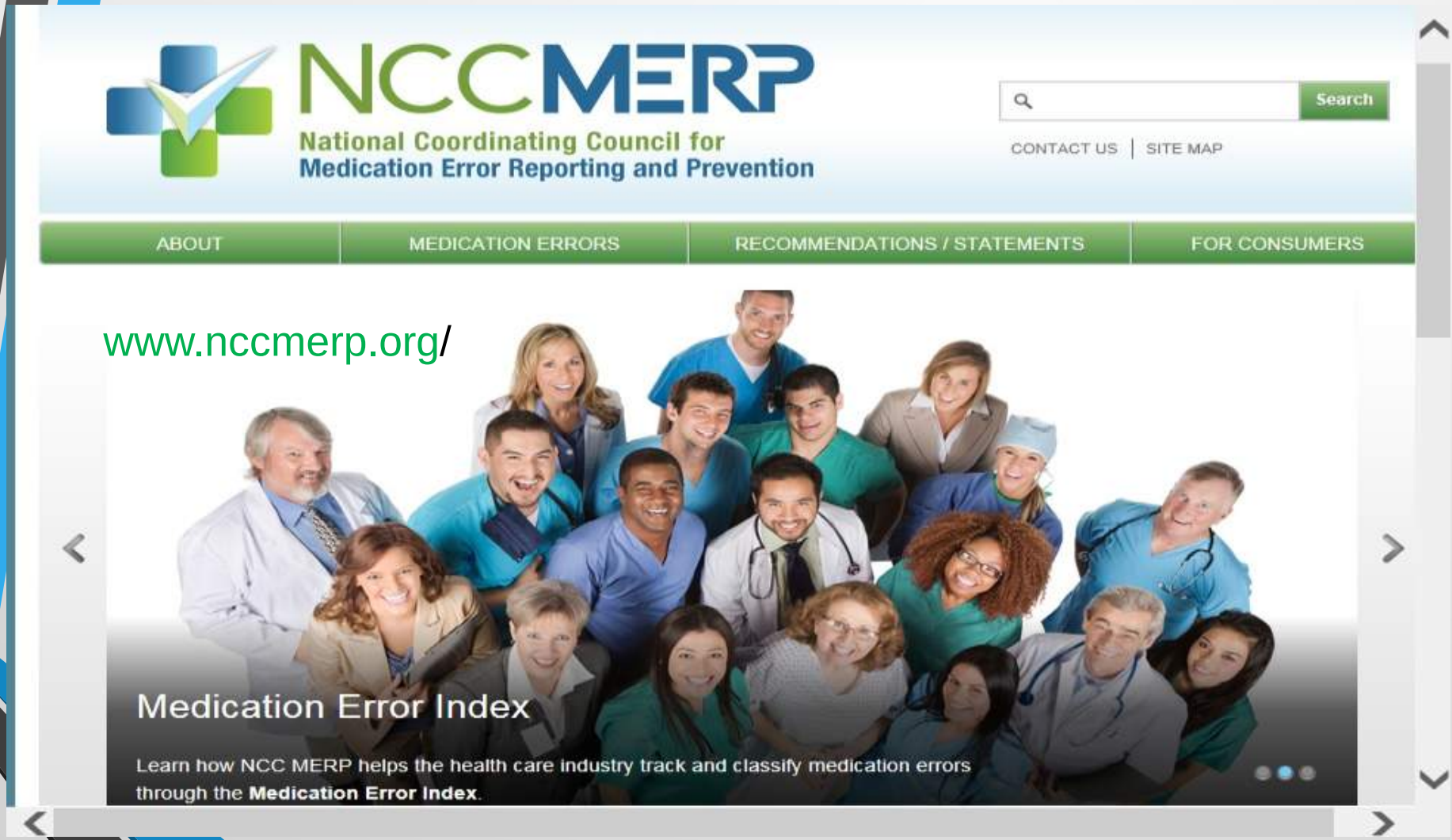
USP U.S. Pharmacopeial



American Society of Health System Pharmacists or ASHP



National Coordinating Council



https://www.nccmerp.org/nan-alert-archive



NCCMERP

National Coordinating Council for Medication Error Reporting and Prevention

Search

CONTACT US | SITE MAP

ABOUT | MEDICATION ERRORS | RECOMMENDATIONS / STATEMENTS | FOR CONSUMERS | OPIOID RESOURCES

NAN Alert Archive

The National Alert Network (NAN) publishes the alerts from the National Medication Errors Reporting Program. NAN encourages the sharing and reporting of medication errors, so that lessons learned can be used to increase the safety of the medication use system.

May 17, 2022	Potassium chloride for injection concentrate in EXCEL plastic bags
Dec 06, 2021	Age-related COVID-19 vaccine mix-ups
Oct 15, 2021	Mix-ups between the influenza (flu) vaccine and COVID-19 vaccines
Sep 09, 2020	Dangerous Wrong-Route Errors with Tranexamic Acid
May 24, 2018	Safe handling of concentrated electrolyte products from outsourcing facilities during critical drug shortages

NAN ALERT

The National Alert Network (NAN) publishes the alerts from the National Medication Errors Reporting Program. NAN encourages the sharing and reporting of medication errors, so that lessons learned can be used to increase the safety of the medication use system.

May 17, 2022
Potassium chloride for injection concentrate in EXCEL plastic bags

› Subscribe › Archive

Medications in the OR ASA Statement

American Society of Anesthesiologists™

www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx

Statement on Security of Medications in the Operating Room

Committee of Oversight: Quality Management and Departmental Administration

(Approved by the ASA Executive Committee in October 2003, and last amended by the ASA House of Delegates on October 17, 2018)

Preamble

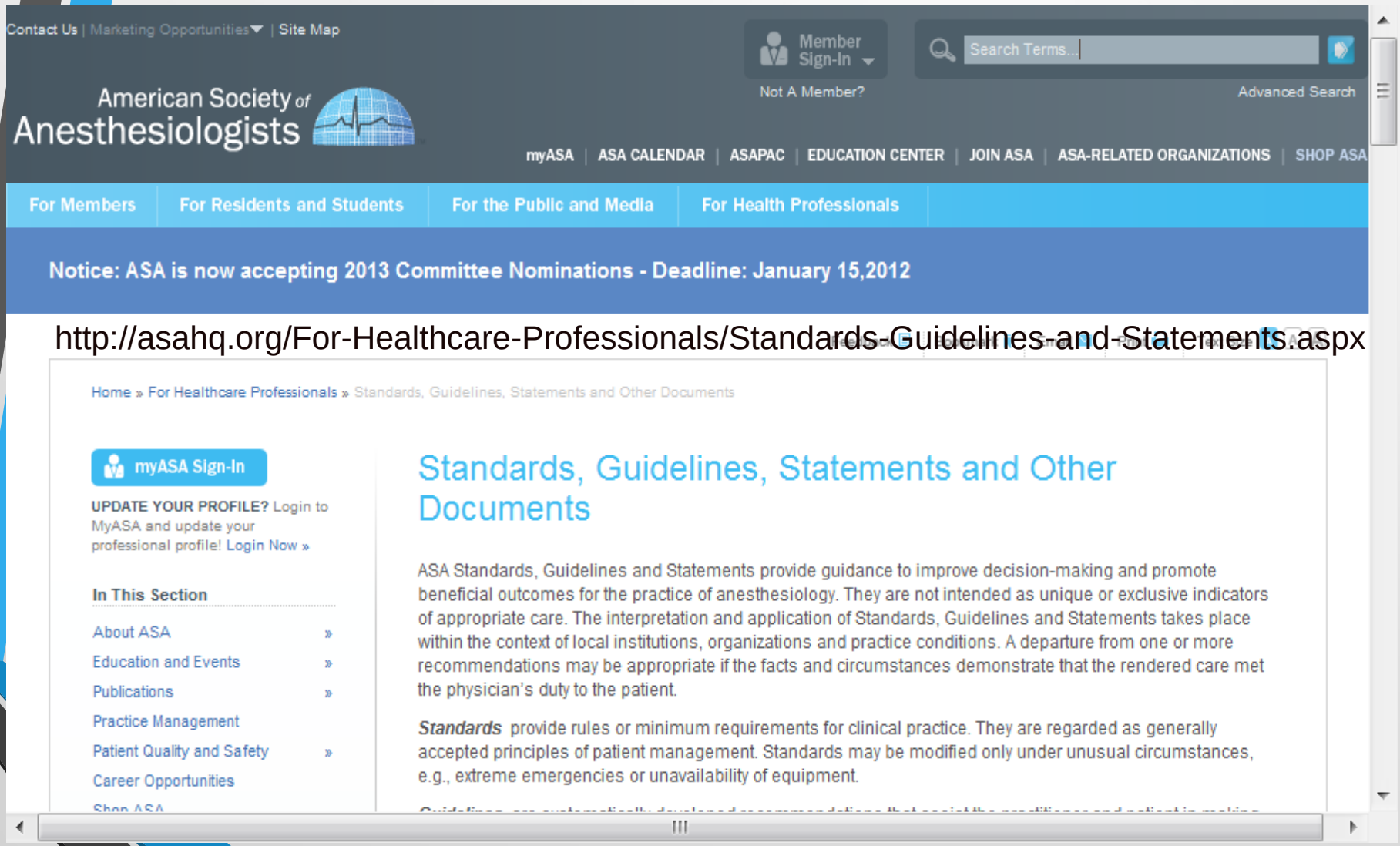
A secure environment of care is necessary for medication safety. Medication safety includes the security of oral, sublingual, parenteral, and inhaled pharmaceutical agents used for elective and emergency patient care. A secure physical area ensures the integrity of anesthesia machines as well as other equipment and materials. Security of medications in the operating room suite is essential for patient safety.

Recommended Policies

1. Access to operating room suites must be strictly limited to authorized persons.
2. All Schedule II through V medications must be kept in locked enclosed areas when not under the direct control of an anesthesia professional.
3. Anesthesia professionals must have immediate access to drugs and equipment required for emergency patient care. Procedures designed to prevent unauthorized access to such drugs must not impede this imperative for patient safety.
4. Anesthesia carts and anesthesia machines may remain unlocked, and non-controlled* medications may be left in or on top of unlocked anesthesia carts or anesthesia machines immediately prior to, during, and immediately following surgical cases in an operating room, so long as there are authorized operating room personnel in the OR suite.

Rationale

ASA Guidelines and Statements



FDA's Compounding Website

www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm





Programs
Topics
Improvement
Leading System Improvement
Chronic Conditions
Critical Care
Developing Countries
End Stage Renal Disease
Flow
Healthcare-Associated Infections
Health Professions Education
HIV/AIDS
Last Phase of Life
Medical-Surgical Care
Office Practices
Patient-Centered Care
Patient Safety
Safety: General
Measures
Changes
Improvement Stories
Tools
Resources
Literature
FAQs
Medication Systems
Reducing Harm from Falls
Surgical Site Infections
Perinatal Care
Reducing Mortality
Reliability
Community
Workspace
Results

Introduction to Trigger Tools for Identifying Adverse Events

The use of "triggers," or clues, to identify adverse events (AEs) is an effective method for measuring the overall level of harm from medical care in a health care organization. Traditional efforts to detect AEs have focused on voluntary reporting and tracking of errors. However, public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent cause no harm to patients. Hospitals need a more effective way to identify events that do cause harm to patients, in order to select and test changes to reduce harm.

There are various Trigger Tools available on IHI.org, including:

- IHI Global Trigger Tool for Measuring Adverse Events
- Trigger Tool for Measuring Adverse Drug Events
- Trigger Tool for Measuring Adverse Drug Events in a Mental Health Setting
- Trigger Tool for Measuring Adverse Drug Events in the Nursing Home
- Surgical Trigger Tool for Measuring Peri-operative Adverse Events
- Intensive Care Unit Adverse Event Trigger Tool
- Pediatric Trigger Toolkit: Measuring Adverse Drug Events in the Children's Hospital
- Trigger Tool for Measuring Adverse Events in the Neonatal Intensive Care Unit
- Outpatient Adverse Event Trigger Tool

These Trigger Tools provide an easy-to-use method for accurately identifying AEs (harm) and measuring the rate of AEs over time. Tracking AEs over time is a useful way to tell if changes being made are improving the safety of the care processes.

Choosing a Tool

There are two approaches to using the harm measures from the Trigger Tools:

1. To monitor an overall level of harm as a "dashboard" item
2. To track harm in a specific topic or area

The **IHI Global Trigger Tool** is designed specifically for the first approach. This is the tool to use for an organization-wide measure that can be reported to leadership. It is designed for use with the records of adult inpatients in acute care.

Related Information
- Measures
- Changes
- Tools
- Improvement Tip: Focus on Harm, Not Errors

Join the Discussion

Free Trigger Tools Listserv

Join a free listserv with other users of IHI Trigger Tools.

1. Send a completely blank email (no subject, signature, or text in message body) to: subscribe-triggertools@ls.ihi.org.

2. You will receive a confirmation message.

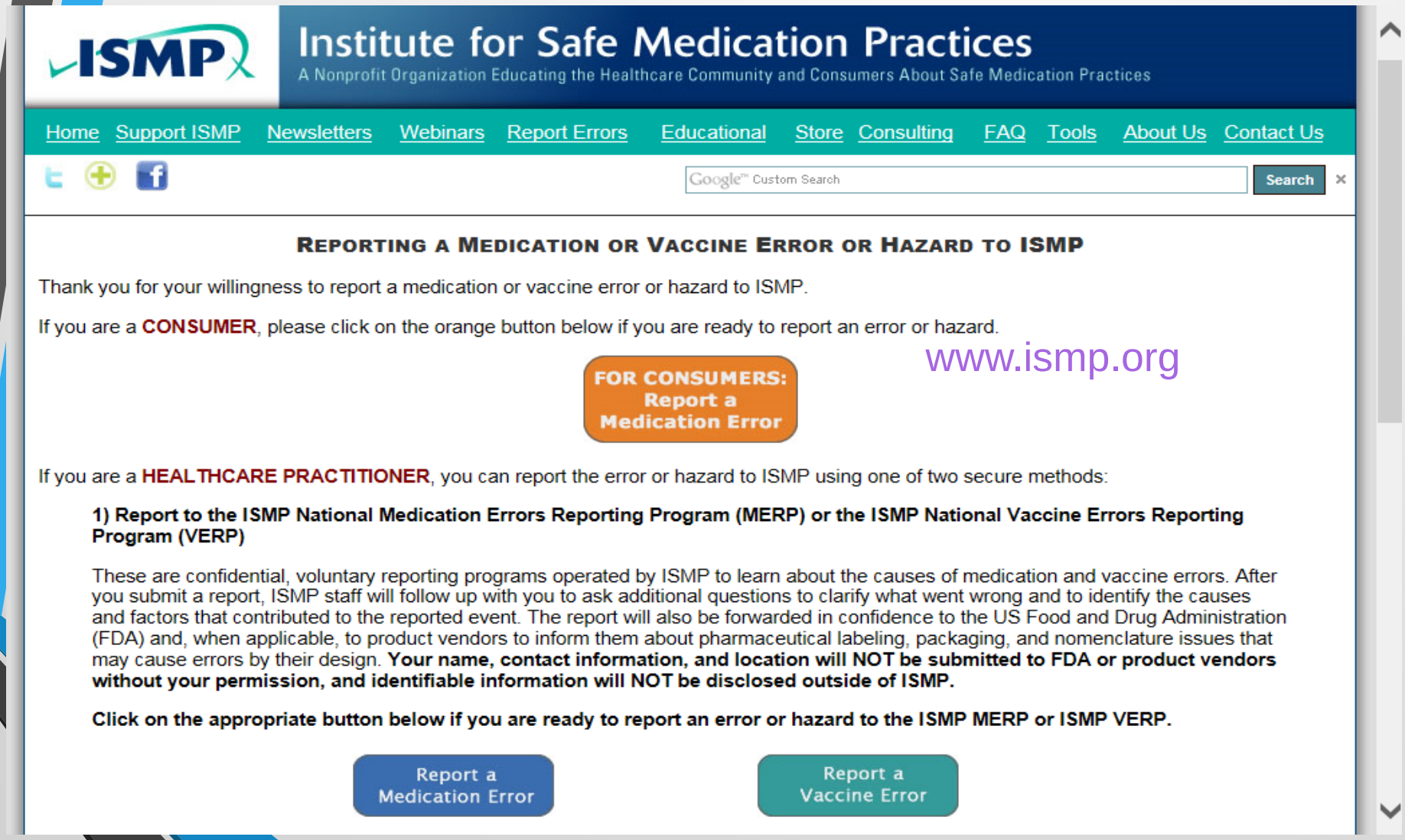
3. Post messages to the listserv by sending emails to triggertools@ls.ihi.org.

Featured Tool

Interactive Trigger Tool for Measuring ADEs

The interactive Trigger Tool makes tracking ADEs over time easier and more accurate, and

ISMP Medication Error Reporting Program



Medication Resources

- Governmental agencies may include
  - Food and Drug Administration (FDA) at www.fda.gov
  - Med Watch Program at www.fda.gov/medwatch
  - Agency for Health Care Research and Quality (AHRQ) at www.ahrq.gov
- Other sites
  - Institute for Safe Medication Practices (ECRI) - www.ismp.org
  - U.S. Pharmacopoeia (USP) www.usp.org
  - Institute for Healthcare Improvement- www.ihi.org (NPSF combined),
  - Sentinel event alerts at www.jointcommission.org

Interactive DRI Tool and Tables

Search FNIC

Go

- Search all USDA
- Advanced Search
- Search Tips

Resources for:

- Consumers

Browse By Subject

- Dietary Guidance
- Lifecycle Nutrition
- Diet and Disease
- Food Composition
- Food Safety
- Weight and Obesity
- Food Labeling
- Dietary Supplements
- Nutrition Assistance Programs
- Surveys, Reports and Research

Dietary Guidance >

Dietary Reference Intakes

The Dietary Reference Intakes (DRIs) are developed and published by the Institutes of Medicine (IOM). The DRIs represent the most current scientific knowledge on nutrient needs of healthy populations. Please note that individual requirements may be higher or lower than the DRIs.



Dietary Reference Intake Calculator for Healthcare Professionals

Easily calculate daily nutrient recommendations for dietary planning based on the National Academy of Sciences' Institute of Medicine's DRI recommendations.



DRI Tables

Find downloadable tables and charts of DRIs for all nutrients categorized by age and sex.



DRI Reports

Find details on how the DRIs were set, including the application of statistically valid methods and the roles nutrients play in traditional deficiency and chronic diseases.

Resources on Individual Macronutrients, Phytonutrients, Vitamins and Minerals

- **Macronutrients** - including general and specific resources on carbohydrates, proteins, fiber, fats and cholesterol, water, as well as interactive tools.
- **Phytonutrients** - including general information, government-related sites, and resources on specific phytonutrients such as tea, lycopene, and

Dietary Guidance

- Dietary Guidelines
  - Previous Editions
  - Historical Dietary Guidance
- Dietary Reference Intakes
  - Dietary Reference Intake Calculator for Healthcare Professionals
  - DRI Nutrient Reports
  - DRI Tables
- Fruits & Veggies-More Matters Resources
  - Fruits & Veggies-More Matters™
  - Fruit and Veggie Pages for...
  - State Programs and Resources
  - Resources in Spanish
- Individual Dietary Assessment
- MyPlate and Historical Food Pyramid Resources